SUBCHAPTER 13P – EMERGENCY MEDICAL SERVICES AND TRAUMA RULES

SECTION .0100 – DEFINITIONS

10A NCAC 13P .0101 ABBREVIATIONS

As used in this Subchapter, the following abbreviations mean:

(1) AHA: American Heart Association;
(2) CPR: Cardiopulmonary Resuscitation;
(3) EMD: Emergency Medical Dispatcher;
(4) EMDPRS: Emergency Medical Dispatch Priority Reference System;
(5) EMS: Emergency Medical Services;
(6) EMS-NP: EMS Nurse Practitioner;
(7) EMS-PA: EMS Physician Assistant;
(8) EMT: Emergency Medical Technician;
(9) EMT-I: EMT-Intermediate;
(10) EMT-P: EMT-Paramedic;
(11) MICN: Mobile Intensive Care Nurse;
(12) MR: Medical Responder;
(13) NHTSA: National Highway Traffic Safety Administration;
(14) OEMS: Office of Emergency Medical Services; and
(15) US DOT: United States Department of Transportation.

History Note: *Authority G.S. 143-508(b);*
Temporary Adoption Eff. January 1, 2002;
Eff. April 1, 2003;
Amended Eff. January 1, 2004.

10A NCAC 13P .0102 AIR MEDICAL AMBULANCE

As used in this Subchapter, "Air Medical Ambulance" means an aircraft specifically designed and equipped to transport patients by air. The patient care compartment of air medical ambulances shall be staffed by medical crew members approved for the mission by the medical director.

History Note: *Authority G.S. 143-508(b); 143-508(d)(8);*
Temporary Adoption Eff. January 1, 2002;
Eff. April 1, 2003.

10A NCAC 13P .0103 AIR MEDICAL PROGRAM

As used in this Subchapter, "Air Medical Program" means a Specialty Care Transport Program designed and operated for transportation of patients by either fixed or rotary wing aircraft.

History Note: *Authority G.S. 143-508(b); 143-508(d)(1);*
Temporary Adoption Eff. January 1, 2002;
Eff. April 1, 2003.

10A NCAC 13P .0104 ASSISTANT MEDICAL DIRECTOR

As used in this Subchapter, "Assistant Medical Director" means a physician, EMS-PA, or EMS-NP who assists the medical director with the medical aspects of the management of an EMS System or EMS Specialty Care Transport Program.

History Note: *Authority G.S. 143-508(b);*
Temporary Adoption Eff. January 1, 2002;
Eff. April 1, 2003.

10A NCAC 13P .0105 CONVALESCENT AMBULANCE

As used in this Subchapter, "Convalescent Ambulance" means an ambulance used on a scheduled basis solely to transport patients having a known non-emergency medical condition. Convalescent ambulances shall not be used in place of any other category of ambulance defined in this Subchapter.

History Note: *Authority G.S. 143-508(b); 143-508(d)(8);*
Temporary Adoption Eff. January 1, 2002;
Eff. April 1, 2003.

10A NCAC 13P .0106 EDUCATIONAL MEDICAL ADVISOR

As used in this Subchapter, "Educational Medical Advisor" means the physician responsible for overseeing the medical components of approved EMS educational programs in continuing education, basic, and advanced EMS educational institutions.

History Note: *Authority G.S. 143-508(b); 143-508(d)(3);*
Temporary Adoption Eff. January 1, 2002;
Eff. April 1, 2003.

10A NCAC 13P .0107 EMS EDUCATIONAL INSTITUTION

As used in this Subchapter, "EMS Educational Institution" means any agency credentialed by the OEMS to offer EMS educational programs.

History Note: *Authority G.S. 143-508(b); 143-508(d)(4);*
Temporary Adoption Eff. January 1, 2002;
Eff. April 1, 2003.

10A NCAC 13P .0108 EMS INSTRUCTOR

History Note: *Authority G.S. 131E-155(a)(7a); 143-508(b); 143-508(d)(3); 143-508(d)(4);*
Temporary Adoption Eff. January 1, 2002;
Repealed Eff. January 1, 2004.

10A NCAC 13P .0109 EMS NONTRANSPORTING VEHICLE

As used in this Subchapter, "EMS Nontransporting Vehicle" means a motor vehicle dedicated and equipped to move medical equipment and EMS personnel functioning within the scope of practice of EMT-I or EMT-P to the scene of a request for assistance. EMS nontransporting vehicles shall not be used for the transportation of patients on the streets, highways, waterways, or airways of the state.

History Note: *Authority G.S. 143-508(b); 143-508(d)(8);*
Temporary Adoption Eff. January 1, 2002;
Eff. April 1, 2003.

10A NCAC 13P .0110 EMS SYSTEM

As used in this Subchapter, "EMS System" means a coordinated arrangement of resources (including personnel, equipment, and facilities) organized to respond to medical emergencies and integrated with other health care providers and networks including, but not limited to, public health, community health monitoring activities, and special needs populations.

History Note: *Authority G.S. 143-508(b);*
Temporary Adoption Eff. January 1, 2002;
Eff. April 1, 2003.

10A NCAC 13P .0111 GROUND AMBULANCE

As used in this Subchapter, "Ground Ambulance" means an ambulance used to transport patients with traumatic or medical conditions or patients for whom the need for emergency or non-emergency medical care is anticipated either at the patient location or during transport.

History Note: *Authority G.S. 143-508(b); 143-508(d)(8);*
Temporary Adoption Eff. January 1, 2002;
Eff. April 1, 2003.

10A NCAC 13P .0112 MEDICAL CREW MEMBERS
As used in this Subchapter, "Medical Crew Member" means EMS personnel or other health care professionals who are licensed or registered in North Carolina and are affiliated with a Specialty Care Transport Program.

History Note: *Authority G.S. 143-508(b); 143-508(d)(3);*
Temporary Adoption Eff. January 1, 2002;
Eff. April 1, 2003.

10A NCAC 13P .0113 MEDICAL DIRECTOR
As used in this Subchapter, "Medical Director" means the physician responsible for the medical aspects of the management of an EMS System or EMS Specialty Care Transport Program.

History Note: *Authority G.S. 143-508(b);*
Temporary Adoption Eff. January 1, 2002;
Eff. April 1, 2003.

10A NCAC 13P .0114 MEDICAL OVERSIGHT
As used in this Subchapter, "Medical Oversight" means the responsibility for the management and accountability of the medical care aspects of an EMS System or Specialty Care Transport Program. Medical Oversight includes physician direction of the initial education and continuing education of EMS personnel or medical crew members; development and monitoring of both operational and treatment protocols; evaluation of the medical care rendered by EMS personnel or medical crew members; participation in system or program evaluation; and directing, by two-way voice communications, the medical care rendered by the EMS personnel or medical crew members.

History Note: *Authority G.S. 143-508(b);*
Temporary Adoption Eff. January 1, 2002;
Eff. April 1, 2003;
Amended Eff. January 1, 2004.

10A NCAC 13P .0115 MODEL EMS SYSTEM
As used in this Subchapter, "Model EMS System" means an approved EMS System that chooses to meet the criteria for and receives this designation by the OEMS.

History Note: *Authority G.S. 143-508(b);*
Temporary Adoption Eff. January 1, 2002;
Eff. April 1, 2003.

10A NCAC 13P .0116 OFFICE OF EMERGENCY MEDICAL SERVICES
As used in this Subchapter, "Office of Emergency Medical Services (OEMS)" means a section of the Division of Health Service Regulation of the North Carolina Department of Health and Human Services located at 701 Barbour Drive, Raleigh, North Carolina 27603.

History Note: *Authority G.S. 143-508(b);*
Temporary Adoption Eff. January 1, 2002;
Eff. April 1, 2003.

10A NCAC 13P .0117 OPERATIONAL PROTOCOLS
As used in this Subchapter, "Operational Protocols" means the written administrative policies and procedures of an EMS System that provide guidance for the day-to-day operation of the system.

History Note: *Authority G.S. 143-508(b);*
Temporary Adoption Eff. January 1, 2002;
Eff. April 1, 2003.

10A NCAC 13P .0118 PHYSICIAN
As used in this Subchapter, "Physician" means a medical or osteopathic doctor licensed by the North Carolina Medical Board to practice medicine in the state of North Carolina.

History Note: *Authority G.S. 143-508(b);*
Temporary Adoption Eff. January 1, 2002;
Eff. April 1, 2003.

10A NCAC 13P .0119 EMS PEER REVIEW COMMITTEE
As used in this Subchapter, "EMS Peer Review Committee" means a committee as defined in G.S. 131E-155(a)(6b).

History Note: *Authority G.S. 131E-155(a)(6b); 143-508(b); 143-518(a)(5);*
Temporary Adoption Eff. January 1, 2002;
Eff. April 1, 2003;
Amended Eff. January 1, 2004.

10A NCAC 13P .0120 SPECIALTY CARE TRANSPORT PROGRAM
As used in this Subchapter, "Specialty Care Transport Program" means a program designed and operated for the provision of specialized medical care and transportation of critically ill or injured patients.

History Note: *Authority G.S. 143-508(b); 143-508(d)(1);*
Temporary Adoption Eff. January 1, 2002;
Eff. April 1, 2003.

10A NCAC 13P .0121 SPECIALTY CARE TRANSPORT PROGRAM CONTINUING EDUCATION COORDINATOR
As used in this Subchapter, "Specialty Care Transport Program Continuing Education Coordinator" means a Level I EMS Instructor within a specialty care transport program who is responsible for the coordination of EMS continuing education programs for EMS personnel within the program.

History Note: *Authority G.S. 143-508(b); 143-508(d)(3); 143-508(d)(13);*
Temporary Adoption Eff. January 1, 2002;
Eff. January 1, 2004.

10A NCAC 13P .0122 SYSTEM CONTINUING EDUCATION COORDINATOR
As used in this Subchapter, "System Continuing Education Coordinator" means a Level I EMS Instructor within a Model EMS System who is responsible for the coordination of EMS continuing education programs.

History Note: *Authority G.S. 143-508(b); 143-508(d)(3); 143-508(d)(13);*
Temporary Adoption Eff. January 1, 2002;
Eff. January 1, 2004.

10A NCAC 13P .0123 TREATMENT PROTOCOLS
As used in this Subchapter, "Treatment Protocols" means a written document approved by the medical directors of both the local EMS System or Specialty Care Transport Program and the OEMS specifying the diagnostic procedures, treatment procedures, medication administration, and patient-care-related policies that shall be completed by EMS personnel or medical crew members based upon the assessment of a patient.

History Note: *Authority G.S. 143-508(b); 143-508(d)(6); 143-508(d)(7);*
Temporary Adoption Eff. January 1, 2002;
Eff. April 1, 2003.

10A NCAC 13P .0124 WATER AMBULANCE

As used in this Subchapter, "Water Ambulance" means a watercraft specifically designed and equipped to transport patients.

History Note: *Authority G.S. 143-508(b); 143-508(d)(8);*
Temporary Adoption Eff. January 1, 2002;
Eff. April 1, 2003.

SECTION .0200 – EMS SYSTEMS

10A NCAC 13P .0201 EMS SYSTEM REQUIREMENTS

(a) County governments shall establish EMS Systems. Each EMS System shall have:

(1) a defined geographical service area for the EMS System. The minimum service area for an EMS System shall be one county. There may be multiple EMS provider service areas within the service area of an EMS System. The highest level of care offered within any EMS provider service area must be available to the citizens within that service area 24 hours per day;

(2) a defined scope of practice for EMS personnel, functioning in the EMS System, within the parameters set forth by the North Carolina Medical Board pursuant to G.S. 143-514;

(3) a written plan describing the dispatch and coordination of all responders that provide EMS care within the system;

(4) at least one licensed EMS provider. For those systems with providers operating within the EMD, EMT-I, or EMT-P scope of practice, there shall be a plan for medical oversight required by Section .0400 of this Subchapter;

(5) an identified number of permitted ambulances to provide coverage to the service area 24 hours per day;

(6) personnel credentialed to perform within the scope of practice of the system and to staff the ambulance vehicles as required by G.S. 131E-158. There shall be a written plan for the use of credentialed EMS personnel for all practice settings used within the system;

(7) a mechanism to collect and electronically submit to the OEMS data that uses the EMS data set and data dictionary as specified in "North Carolina College of Emergency Physicians: Standards for Medical Oversight and Data Collection," incorporated by reference in accordance with G.S. 150B-21.6, including subsequent amendments and additions. This document is available from the OEMS, 2707 Mail Service Center, Raleigh, North Carolina 27699-2707, at no cost. EMS Systems shall comply with this requirement by July 1, 2004;

(8) a written infection control policy that addresses the cleansing and disinfecting of vehicles and equipment that are used to treat or transport patients;

(9) a written plan to provide orientation to personnel on EMS operations and related issues for hospitals routinely receiving patients from the EMS System;

(10) a listing of facilities that will provide online medical direction for systems with providers operating within the EMT, EMT-I, or EMT-P scope of practice. To provide online medical direction, the facility shall have:

(A) availability of a physician, MICN, EMS-NP, or EMS-PA to provide online medical direction to EMS personnel during all hours of operation of the facility;

(B) a written plan to provide physician backup to the MICN, EMS-NP, or EMS-PA providing online medical direction to EMS personnel;

(C) a mechanism for persons providing online medical direction to provide feedback to the EMS Peer Review Committee; and

(D) a written plan to provide orientation and education regarding treatment protocols for those individuals providing online medical direction;

(11) a written plan to ensure that each facility that routinely receives patients and also offers clinical education for EMS personnel provides orientation and education to all preceptors regarding requirements of the EMS System;

(12) a written plan for providing emergency vehicle operation education for system personnel who operate emergency vehicles;

(13) an EMS communication system that provides for:
  (A) public access using the emergency telephone number 9-1-1 within the public dial telephone network as the primary method for the public to request emergency assistance. This number shall be connected to the emergency communications center or Public Safety Answering Point (PSAP) with immediate assistance available such that no caller will be instructed to hang up the telephone and dial another telephone number. A person calling for emergency assistance shall never be required to speak with more than two persons to request emergency medical assistance;
  (B) an emergency communications system operated by public safety telecommunicators with training in the management of calls for medical assistance available 24 hours per day;
  (C) dispatch of the most appropriate emergency medical response unit or units to any caller's request for assistance. The dispatch of all response vehicles shall be in accordance with an official written EMS System plan for the management and deployment of response vehicles including requests for mutual aid; and
  (D) two-way radio voice communications from within the defined service area to the emergency communications center or PSAP and to facilities where patients are routinely transported. The emergency communications system shall maintain all Federal Communications Commission (FCC) radio licenses or authorizations required;

(14) a written plan addressing the use of Specialty Care Transport Programs within the system;

(15) a written continuing education plan for credentialed EMS personnel that follows the guidelines of the:
  (A) "US DOT NHTSA First Responder Refresher: National Standard Curriculum" for MR personnel;
  (B) "US DOT NHTSA EMT-Basic Refresher: National Standard Curriculum" for EMT personnel;
  (C) "EMT-P and EMT-I Continuing Education National Guidelines" for EMT-I and EMT-P personnel; and
  (D) "US DOT NHTSA Emergency Medical Dispatcher: National Standard Curriculum" for EMD personnel.

  These documents are incorporated by reference in accordance with G.S. 150B-21.6, including subsequent amendments and additions. These documents are available from NHTSA, 400 7th Street, SW, Washington, D.C. 20590, at no cost; and

(16) a written plan addressing the orientation of MICN, EMS-NP, or EMS-PA used in the system. The orientation program shall include the following:
  (A) a discussion of all EMS System treatment protocols and procedures;
  (B) an explanation of the specific scope of practice for credentialed EMS personnel, as authorized by the approved EMS System treatment protocols as required by Rule .0405 of this Chapter;
  (C) a discussion of all practice settings within the EMS System and how scope of practice may vary in each setting;
  (D) a mechanism to assess the student's ability to effectively use EMS System communications equipment including hospital and prehospital devices, EMS communication protocols, and communications contingency plans as related to on-line medical direction; and
  (E) the successful completion of a scope of practice evaluation administered under the direction of the medical director.

(b) An application to establish an EMS System shall be submitted by the county to the OEMS for review. When the system is comprised of more than one county, only one application shall be submitted. The proposal shall demonstrate that the system meets the requirements in Paragraph (a) of this Rule. System approval shall be granted for a period of six years. Systems shall apply to OEMS for reapproval.

History Note: *Authority G.S. 131E-155(a)(8), (a)(9), (a)(15); 143-508(b); (d)(1), (d)(5), (d)(9); 143-509(1); 143-517; Temporary Adoption Eff. January 1, 2002;*
Eff. August 1, 2004.

10A NCAC 13P .0202 MODEL EMS SYSTEMS

(a) Some EMS Systems may choose to move beyond the minimum requirements in Rule .0201 of this Section and receive designation from the OEMS as a Model EMS System. To receive this designation, an EMS System shall document that, in addition to the system requirements in Rule .0201 of this Section, the following criteria have been met:

(1) a uniform level of care throughout the system available 24 hours per day;

(2) a plan for medical oversight that meets the requirements found in Section .0400 of this Subchapter. Specifically, Model EMS Systems shall meet the additional requirements for medical director and written treatment protocols as defined in Rules .0401(1)(b) and .0405(a)(2) of this Subchapter;

(3) a mechanism to collect and electronically submit to the OEMS data that use the EMS data set and data dictionary as specified in "North Carolina College of Emergency Physicians: Standards for Medical Oversight and Data Collection," incoporated by reference in accordance with G.S. 150B-21.6, including subsequent amendments and additions. This document is available from the OEMS, 2707 Mail Service Center, Raleigh, North Carolina 27699-2707, at no cost;

(4) a written plan to address management of the EMS System to include:
   (A) triage of patients to appropriate facilities;
   (B) transport of patients to facilities outside of the system;
   (C) arrangements for transporting patients to appropriate facilities when diversion or bypass plans are activated;
   (D) a mechanism for reporting, monitoring, and establishing standards for system response times;
   (E) a disaster plan; and
   (F) a mass-gathering plan;

(5) a written continuing education plan for EMS personnel, under the direction of the System Continuing Education Coordinator, developed and modified based on feedback from system data, review, and evaluation of patient outcomes and quality management reviews;

(6) a written plan to assure participation in clinical and field internship educational components for all EMS personnel;

(7) operational protocols for the management of equipment, supplies and medications. These protocols shall include a methodology:
   (A) to assure that each vehicle contains the required equipment and supplies on each response;
   (B) for cleaning and maintaining the equipment and vehicles; and
   (C) to assure that supplies and medications are not used beyond the expiration date and stored in a temperature controlled atmosphere according to manufacturer's specifications;

(8) a written plan for the systematic and periodic inspection, repair and maintenance of all vehicles used in the system;

(9) a written plan addressing the role of the EMS System in the areas of public education, injury prevention, and community health;

(10) affiliation with at least one trauma Regional Advisory Committee; and

(11) a system-wide communication system that meets the requirements of Paragraph (a)(13) of Rule .0201 of this Section, and in addition:
   (A) operates an EMD program; and
   (B) has an operational E-911 system.

(b) EMS Systems holding current accreditation by a national accreditation agency may use this as documentation of completion of the equivalent requirements outlined in this Rule.

(c) The county shall submit an application for designation as a Model EMS System to the OEMS for review. When the system is comprised of more than one county, only one application shall be submitted. The application shall demonstrate that the system meets the standards found in Paragraph (a) of this Rule. Designation as a Model EMS System shall be awarded for a period of six years. Systems shall apply to OEMS for model system redesignation.

History Note: *Authority G.S. 143-508(b); (d)(1), (d)(5), (d)(9); 143-509(1); 143-508(d)(13);*
Temporary Adoption Eff. January 1, 2002;
Eff. January 1, 2004.

10A NCAC 13P .0203 SPECIAL SITUATIONS

Upon application of citizens in North Carolina, the North Carolina Medical Care Commission shall approve the furnishing and providing of programs within the scope of practice of EMD, EMT, EMT-I, or EMT-P in North Carolina by persons who have been approved to provide these services by an agency of a state adjoining North Carolina or federal

jurisdiction. This approval shall be granted where the North Carolina Medical Care Commission concludes that the requirements enumerated in Rule .0201 of this Subchapter cannot be reasonably obtained by reason of lack of geographical access.

History Note: *Authority G.S. 143-508(b);*
Temporary Adoption Eff. January 1, 2002;
Eff. April 1, 2003;
Amended Eff. January 1, 2004.

10A NCAC 13P .0204 EMS PROVIDER LICENSE REQUIREMENTS

(a) Any firm, corporation, agency, organization or association that provides emergency medical services as its primary responsibility shall be licensed as an EMS Provider by meeting the following criteria:

(1) Be affiliated with an EMS System;
(2) Present an application for a permit for any ambulance that will be in service as required by G.S. 131E-156;
(3) Submit a written plan detailing how the Provider will furnish credentialed personnel;
(4) Where there is a franchise ordinance in effect that covers the proposed service area, be granted a current franchise to operate or present written documentation of impending receipt of a franchise from the county; and
(5) Present a written plan and method for recording systematic, periodic inspection repair, cleaning, and routine maintenance of all EMS responding vehicles.

(b) An EMS Provider may renew its license by presenting documentation to the OEMS that the Provider meets the criteria found in Paragraph (a) of this Rule.

History Note: *Authority G.S. 131E-155.1(c);*
Temporary Adoption Eff. January 1, 2002;
Eff. April 1, 2003;
Amended Eff January 1, 2004.

10A NCAC 13P .0205 EMS PROVIDER LICENSE CONDITIONS

(a) Applications for an EMS Provider License must be received by the OEMS at least 30 days prior to the date that the Provider proposes to initiate service. Applications for renewal of an EMS Provider License must be received by the OEMS at least 30 days prior to the expiration date of the current license.
(b) Only one license shall be issued to each EMS Provider. The Department shall issue a license to the EMS Provider following verification of compliance with applicable laws and rules.
(c) EMS Provider Licenses shall not be transferred.
(d) The license shall be posted in a prominent location accessible to public view at the primary business location of the EMS Provider.

History Note: *Authority G.S. 131E-155.1(c);*
Temporary Adoption Eff. January 1, 2002;
Eff. April 1, 2003;
Amended Eff. January 1, 2004.

10A NCAC 13P .0206 TERM OF EMS PROVIDER LICENSE

(a) EMS Provider Licenses shall remain in effect unless any of the following occurs:

(1) the Department imposes an administrative sanction which specifies license expiration;
(2) the EMS provider closes or goes out of business;
(3) the EMS provider changes name or ownership; or
(4) substantial failure to continue to comply with Rule .0204 of this Section.

(b) When the name or ownership of the EMS provider changes, an EMS Provider License application shall be submitted to the OEMS at least 30 days prior to the effective date of the change.
(c) For EMS providers maintaining affiliation with a Model EMS System, licenses may be renewed without requirement for submission of an application.

History Note: *Authority G.S. 131E-155.1(c);*
Temporary Adoption Eff. January 1, 2002;
Eff. April 1, 2003.

10A NCAC 13P .0207 GROUND AMBULANCE: VEHICLE AND EQUIPMENT REQUIREMENTS

(a) To be permitted as a Ground Ambulance, a vehicle shall have:

(1) a patient compartment that meets the following interior dimensions:
  (A) the length, measured on the floor from the back of the driver's compartment, driver's seat or partition to the inside edge of the rear loading doors, shall be at least 102 inches; and
  (B) the height shall be at least 48 inches over the patient area, measured from the approximate center of the floor, exclusive of cabinets or equipment;

(2) patient care equipment and supplies as defined in the treatment protocols for the system. Vehicles used by EMS providers that are not required to have treatment protocols shall have patient care equipment and supplies as defined in the "North Carolina College of Emergency Physicians: Standards for Medical Oversight and Data Collection," incorporated by reference in accordance with G.S. 150B-21.6, including subsequent amendments and editions. This document is available from the OEMS, 2707 Mail Service Center, Raleigh, North Carolina 27699-2707, at no cost. The equipment and supplies shall be clean, in working order, and secured in the vehicle;

(3) other equipment to include:
  (A) one fire extinguisher mounted in a quick release bracket that shall either be a dry chemical or all-purpose type and have a pressure gauge; and
  (B) the availability of one pediatric restraint device to safely transport pediatric patients under 20 pounds in the patient compartment of the ambulance;

(4) the name of the ambulance provider permanently displayed on each side of the vehicle;

(5) reflective tape affixed to the vehicle such that there is reflectivity on all sides of the vehicle;

(6) emergency warning lights and audible warning devices mounted on the vehicle as required by G.S. 20-125 in addition to those required by Federal Motor Vehicle Safety Standards. All warning devices shall function properly;

(7) no structural or functional defects that may adversely affect the patient, the EMS personnel, or the safe operation of the vehicle;

(8) an operational two-way radio that shall:
  (A) be mounted to the ambulance and installed for safe operation and controlled by the ambulance driver;
  (B) have sufficient range, radio frequencies, and capabilities to establish and maintain two-way voice radio communication from within the defined service area of the EMS System to the emergency communications center or public safety answering point (PSAP) designated to direct or dispatch the deployment of the ambulance;
  (C) be capable of establishing two-way voice radio communication from within the defined service area to the emergency department of the hospital(s) where patients are routinely transported and to facilities that provide on-line medical direction to EMS personnel;
  (D) be equipped with a radio control device mounted in the patient compartment capable of operation by the patient attendant to receive on-line medical direction; and
  (E) be licensed or authorized by the Federal Communications Commission (FCC).

(b) Ground ambulances shall not use a radiotelephone device such as a cellular telephone as the only source of two-way radio voice communication.

(c) Other communication instruments or devices such as data radio, facsimile, computer, or telemetry radio shall be in addition to the mission dedicated dispatch radio and shall function independently from the mission dedicated radio.

History Note: *Authority G.S. 131E-157(a); 143-508(d)(8);*
Temporary Adoption Eff. January 1, 2002;
Eff. April 1, 2003;
Amended Eff. January 1, 2004.

10A NCAC 13P .0208 CONVALESCENT AMBULANCE: VEHICLE AND EQUIPMENT REQUIREMENTS

(a) To be permitted as a Convalescent Ambulance, a vehicle shall have:

(1) a patient compartment that meets the following interior dimensions:

(A) the length, measured on the floor from the back of the driver's compartment, driver's seat or partition to the inside edge of the rear loading doors, shall be at least 102 inches; and

(B) the height shall be at least 48 inches over the patient area, measured from the approximate center of the floor, exclusive of cabinets or equipment;

(2) patient care equipment and supplies as defined in the treatment protocols for the system. Vehicles used by EMS providers that are not required to have treatment protocols shall have patient care equipment and supplies as defined in the "North Carolina College of Emergency Physicians: Standards for Medical Oversight and Data Collection," incorporated by reference in accordance with G.S. 150B-21.6, including subsequent amendments and editions. This document is available from the OEMS, 2707 Mail Service Center, Raleigh, North Carolina 27699-2707, at no cost. The equipment and supplies shall be clean, in working order, and secured in the vehicle;

(3) other equipment to include:

(A) one fire extinguisher mounted in a quick release bracket that shall either be a dry chemical or all-purpose type and have a pressure gauge; and

(B) the availability of one pediatric restraint device to safely transport pediatric patients under 20 pounds in the patient compartment of the ambulance.

(b) Convalescent Ambulances shall:

(1) not be equipped, permanently or temporarily, with any emergency warning devices, audible or visual, other than those required by Federal Motor Vehicle Safety Standards;

(2) have the name of the ambulance provider permanently displayed on each side of the vehicle;

(3) not have emergency medical symbols, such as the Star of Life, block design cross, or any other medical markings, symbols, or emblems, including the word "EMERGENCY," on the vehicle;

(4) have the words "CONVALESCENT AMBULANCE" lettered on both sides and on the rear of the vehicle body; and

(5) have reflective tape affixed to the vehicle such that there is reflectivity on all sides of the vehicle.

(c) A two-way radio or radiotelephone device such as a cellular telephone shall be available to summon emergency assistance for a vehicle permitted as a convalescent ambulance.

(d) The convalescent ambulance shall not have structural or functional defects that may adversely affect the patient, the EMS personnel, or the safe operation of the vehicle.

History Note: *Authority G.S. 131E-157(a); 143-508(d)(8);*
Temporary Adoption Eff. January 1, 2002;
Eff. April 1, 2003;
Amended Eff. January 1, 2004.

10A NCAC 13P .0209 AIR MEDICAL AMBULANCE: VEHICLE AND EQUIPMENT REQUIREMENTS

To be permitted as an Air Medical Ambulance, an aircraft shall meet the following requirements:

(1) Configuration of the aircraft interior shall not compromise the ability to provide appropriate care or prevent providers from performing emergency procedures if necessary.

(2) The aircraft shall have on board patient care equipment and supplies as defined in the treatment protocols for the program. Air Medical Ambulances used by EMS providers that are not required to have treatment protocols shall have patient care equipment and supplies as defined in the "North Carolina College of Emergency Physicians: Standards for Medical Oversight and Data Collection," incorporated by reference in accordance with G.S. 150B-21.6, including subsequent amendments and editions. This document is available from the OEMS, 2707 Mail Service Center, Raleigh, North Carolina 27699-2707, at no cost. The equipment and supplies shall be clean, in working order, and secured in the vehicle.

(3) There shall be installed in the aircraft an internal voice communication system to allow for communication between the medical crew and flight crew.

(4) Due to the different configurations and space limitations of air medical ambulances, the medical director shall designate the combination of medical equipment specified in Item (2) of this Rule that is carried on a mission based on anticipated patient care needs.

(5) Air Medical Ambulances shall have the name of the organization permanently displayed on each side of the aircraft.

(6) Air Medical Ambulances shall be equipped with a two-way voice radio licensed by the Federal Communications Commission capable of operation on any frequency required to allow communications with public safety agencies such as fire departments, police departments, ambulance and rescue units, hospitals, and local government agencies within the defined service area.

(7) All rotary wing aircraft permitted as an air medical ambulance shall have the following flight equipment operational in the aircraft:
- (a) two 360-channel VHF aircraft frequency transceivers;
- (b) one VHF omnidirectional ranging (VOR) receiver;
- (c) attitude indicators;
- (d) one transponder with 4097 code, Mode C with altitude encoding;
- (e) turn and slip indicator in the absence of three attitude indicators;
- (f) current FAA approved navigational aids and charts for the area of operations;
- (g) radar altimeter;
- (h) Satellite Global Navigational System;
- (i) Emergency Locator Transmitter (ELT);
- (j) a remote control external search light;
- (k) a light which illuminates the tail rotor;
- (l) a fire extinguisher; and
- (m) survival gear appropriate for the service area and the number of occupants.

(8) Any fixed wing aircraft issued a permit to operate as an air medical ambulance shall have a current "Instrument Flight Rules" certification.

(9) The availability of one pediatric restraint device to safely transport pediatric patients under 20 pounds in the patient compartment of the air medical ambulance.

(10) The Air Medical Ambulance shall not have structural or functional defects that may adversely affect the patient, the EMS personnel, or the safe operation of the aircraft.

History Note: *Authority G.S. 131E-157(a); 143-508(d)(8);*
Temporary Adoption Eff. January 1, 2002;
Eff. April 1, 2003;
Amended Eff. January 1, 2004.

10A NCAC 13P .0210 WATER AMBULANCE: WATERCRAFT AND EQUIPMENT REQUIREMENTS

To be permitted as a Water Ambulance, a watercraft shall meet the following requirements:

(1) The watercraft shall have a patient care area that:
- (a) provides access to the head, torso, and lower extremities of the patient while providing sufficient working space to render patient care;
- (b) is covered to protect the patient and EMS personnel from the elements; and
- (c) has an opening of sufficient size to permit the safe loading and unloading of a person occupying a litter.

(2) The watercraft shall have on board patient care equipment and supplies as defined in the treatment protocols for the system. Water ambulances used by EMS providers that are not required to have treatment protocols shall have patient care equipment and supplies as defined in the "North Carolina College of Emergency Physicians: Standards for Medical Oversight and Data Collection," incorporated by reference in accordance with G.S. 150B-21.6, including subsequent amendments and editions. This document is available from the OEMS, 2707 Mail Service Center, Raleigh, North Carolina 27699-2707, at no cost. The equipment and supplies shall be clean, in working order, and secured in the vehicle.

(3) Water ambulances shall have the name of the ambulance provider permanently displayed on each side of the watercraft.

(4) Water ambulances shall have a 360-degree beacon warning light in addition to warning devices required in Chapter 75A, Article 1, of the North Carolina General Statutes.

(5) Water ambulances shall be equipped with:

(a) two floatable rigid long backboards with proper accessories for securing infant, pediatric, and adult patients and stabilization of the head and neck;
(b) one floatable litter with patient restraining straps and capable of being secured to the watercraft;
(c) one fire extinguisher mounted in a quick release bracket that shall either be a dry chemical or all-purpose type and have a pressure gauge;
(d) lighted compass;
(e) radio navigational aids such as ADF (automatic directional finder), Satellite Global Navigational System, navigational radar, or other comparable radio equipment suited for water navigation;
(f) marine radio; and
(g) the availability of one pediatric restraint device to safely transport pediatric patients under 20 pounds in the patient compartment of the ambulance;

(6) The water ambulance shall not have structural or functional defects that may adversely affect the patient, the EMS personnel, or the safe operation of the watercraft.

History Note: *Authority G.S. 131E-157(a); 143-508(d)(8);*
Temporary Adoption Eff. January 1, 2002;
Eff. April 1, 2003;
Amended Eff. January 1, 2004.

10A NCAC 13P .0211 AMBULANCE PERMIT CONDITIONS

(a) An EMS provider shall apply to the OEMS for the appropriate Ambulance Permit prior to placing an ambulance in service.
(b) The Department shall issue a permit for an ambulance following verification of compliance with applicable laws and rules.
(c) Only one Ambulance Permit shall be issued for each ambulance.
(d) An ambulance shall be permitted in only one category.
(e) Ambulance Permits shall not be transferred except in the case of Air Medical Ambulance replacement aircraft when the primary aircraft is out of service.
(f) The Ambulance Permit shall be posted as designated by the OEMS inspector.

History Note: *Authority G.S. 131E-157(a); 143-508(d)(8);*
Temporary Adoption Eff. January 1, 2002;
Eff. April 1, 2003;
Amended Eff. January 1, 2004.

10A NCAC 13P .0212 TERM OF AMBULANCE PERMIT

(a) Ambulance Permits shall remain in effect unless any of the following occurs:
(1) The Department imposes an administrative sanction which specifies permit expiration;
(2) The EMS provider closes or goes out of business;
(3) The EMS provider changes name or ownership; or
(4) Substantial failure to comply with the applicable Paragraphs of Rules .0207, .0208, .0209, or .0210 of this Section.

(b) Ambulance Permits shall be renewed without OEMS inspection for those ambulances currently operated within a Model EMS System.

History Note: *Authority G.S. 131E-157(a); 143-508(d)(8);*
Temporary Adoption Eff. January 1, 2002;
Eff. April 1, 2003.

10A NCAC 13P .0213 EMS NONTRANSPORTING VEHICLE REQUIREMENTS

(a) To be permitted as an EMS Nontransporting Vehicle, a vehicle shall:
(1) have patient care equipment and supplies as defined in the treatment protocols for the system. The equipment and supplies shall be clean, in working order, and secured in the vehicle.

(2) have the name of the organization permanently displayed on each side of the vehicle.
(3) have reflective tape affixed to the vehicle such that there is reflectivity on all sides of the vehicle.
(4) have emergency warning lights and audible warning devices mounted on the vehicle as required by G.S. 20-125 in addition to those required by Federal Motor Vehicle Safety Standards. All warning devices shall function properly.
(5) not have structural or functional defects that may adversely affect the EMS personnel or the safe operation of the vehicle.
(6) have one fire extinguisher that shall be a dry chemical or all-purpose type with a pressure gauge, mounted in a quick-release bracket.
(7) have an operational two-way radio that shall:
(A) be mounted to the EMS Nontransporting Vehicle and installed for safe operation and controlled by the driver;
(B) have sufficient range, radio frequencies, and capabilities to establish and maintain two-way voice radio communication from within the defined service area of the EMS System to the emergency communications center or public safety answering point (PSAP) designated to direct or dispatch the deployment of the ambulance;
(C) be capable of establishing two-way voice radio communication from within the defined service area to facilities that provide on-line medical direction to EMS personnel; and
(D) be licensed or authorized by the Federal Communications Commission (FCC).
(8) not use a radiotelephone device such as a cellular telephone as the only source of two-way radio voice communication.

(b) Other communication instruments or devices such as data radio, facsimile, computer, or telemetry radio shall be in addition to the mission dedicated dispatch radio and shall function independently from the mission-dedicated radio.

History Note: *Authority G.S. 143-508(d)(8);*
Temporary Adoption Eff. January 1, 2002;
Eff. April 1, 2003.

10A NCAC 13P .0214 EMS NONTRANSPORTING VEHICLE PERMIT CONDITIONS

(a) An EMS provider shall apply to the OEMS for an EMS Nontransporting Vehicle Permit prior to placing such a vehicle in service.
(b) The Department shall issue a permit for a vehicle following verification of compliance with applicable laws and rules.
(c) Only one EMS Nontransporting Vehicle Permit shall be issued for each vehicle.
(d) EMS Nontransporting Vehicle Permits shall not be transferred.
(e) The EMS Nontransporting Vehicle Permit shall be posted as designated by the OEMS inspector.

History Note: *Authority G.S. 143-508(d)(8);*
Temporary Adoption Eff. January 1, 2002;
Eff. April 1, 2003;
Amended Eff. January 1, 2004.

10A NCAC 13P .0215 TERM OF EMS NONTRANSPORTING VEHICLE PERMIT

(a) EMS Nontransporting Vehicle Permits shall remain in effect for two years in an EMS System or four years in a Model EMS System, unless any of the following occurs:
(1) The Department imposes an administrative sanction that specifies permit expiration;
(2) The EMS provider closes or goes out of business;
(3) The EMS provider changes name or ownership; or
(4) Substantial failure to comply with Rule .0213 of this Section.

(b) EMS Nontransporting Vehicle Permits shall be renewed without OEMS inspection for those vehicles currently operated within a Model EMS System.

History Note: *Authority G.S. 143-508(d)(8);*
Temporary Adoption Eff. January 1, 2002;
Eff. April 1, 2003.

10A NCAC 13P .0216 WEAPONS AND EXPLOSIVES FORBIDDEN

(a) Weapons, as defined by the local county district attorney's office, and explosives shall not be worn or carried aboard an ambulance or EMS nontransporting vehicle within the State of North Carolina when the vehicle is operating in any patient treatment or transport capacity or is available for such function.

(b) This Rule shall apply whether or not such weapons and explosives are concealed or visible.

(c) This Rule shall not apply to duly appointed law enforcement officers.

(d) Safety flares are authorized for use on an ambulance with the following restrictions:

(1) These devices are not stored inside the patient compartment of the ambulance; and

(2) These devices shall be packaged and stored so as to prevent accidental discharge or ignition.

History Note: *Authority G.S. 131E-157(a); 143-508(d)(8);*
Temporary Adoption Eff. January 1, 2002;
Eff. April 1, 2003.

SECTION .0300 – SPECIALTY CARE TRANSPORT PROGRAMS

10A NCAC 13P .0301 PROGRAM CRITERIA

(a) Programs seeking designation to provide specialty care transports shall submit an application for program approval to the OEMS at least 60 days prior to field implementation. The application shall document that the program has:

(1) a defined service area;

(2) a medical oversight plan meeting the requirements of Section .0400;

(3) service continuously available on a 24 hour per day basis;

(4) the capability to provide the following patient care skills and procedures:

(A) advanced airway techniques including rapid sequence induction, cricothyrotomy, and ventilator management, including continuous monitoring of the patient's oxygenation;

(B) insertion of femoral lines;

(C) maintaining invasive monitoring devices to include central venous pressure lines, arterial and venous catheters, arterial lines, intra-ventricular catheters, and epidural catheters; and

(D) interpreting 12-lead electrocardiograms;

(5) a written continuing education plan for EMS personnel, under the direction of the Specialty Care Transport Program Continuing Education Coordinator, developed and modified based on feedback from program data, review and evaluation of patient outcomes, and quality management reviews.

(6) a mechanism to collect and electronically submit to the OEMS data that uses the EMS data set and data dictionary as specified in "North Carolina College of Emergency Physicians: Standards for Medical Oversight and Data Collection," incorporated by reference in accordance with G.S. 150B-21.6, including subsequent amendments and editions. This document is available from the OEMS, 2707 Mail Service Center, Raleigh, North Carolina 27699-2707, at no cost. EMS Specialty Care Transport Programs shall comply with this requirement by July 1, 2004.

(b) Applications for specialty care transport program approval shall document that the applicant meets the requirements for the specific program type or types applied for as specified in Rules .0302, .0303 or .0304 of this Section.

(c) Specialty care transport program approval shall be valid for a period to coincide with the EMS Provider License, not to exceed six years. Programs shall apply to the OEMS for reapproval.

History Note: *Authority G.S. 143-508(d)(1), (d)(8), (d)(9); 143-508(d)(13);*
Temporary Adoption Eff. January 1, 2002;
Eff. January 1, 2004.

10A NCAC 13P .0302 AIR MEDICAL SPECIALTY CARE TRANSPORT PROGRAM

(a) In addition to the general requirements of Specialty Care Transport Programs in Rule .0301 of this Section, Air Medical Programs shall document that the program has:

(1) Medical crew members that have all completed training regarding:

(A) Altitude physiology;

(B) The operation of the EMS communications system used in the program;

(C) In-flight emergencies specific to the aircraft used in the program; and

(D) Aircraft safety. This training shall be conducted every six months.

(2) A Certificate of Need obtained from the Department when applicable;

(3) A written plan for transporting patients to appropriate facilities when diversion or bypass plans are activated;

(4) A written plan for providing emergency vehicle operation education for program personnel who operate ground emergency vehicles; and

(5) A written plan specifying how EMS Systems will request ground support ambulances operated by the program.

(b) Air Medical Programs based outside of North Carolina that provide specialty care transports may be granted approval by the OEMS to operate in North Carolina by submitting an application for program approval. The application shall document that the program meets all criteria specified in Rules .0204 and .0301 of this Subchapter and Paragraph (a) of this Rule.

History Note: *Authority G.S. 143-508(d)(1), (d)(3);*
Temporary Adoption Eff. January 1, 2002;
Eff. April 1, 2003.

10A NCAC 13P .0303 GROUND SPECIALTY CARE TRANSPORT PROGRAMS

(a) When transporting patients that have a medical need for one or more of the skills or procedures as defined for specialty care transport programs in .0301(a)(4) of this Section, staffing for the vehicle used in the ground specialty care transport program shall be at a level to ensure the capability to provide in the patient compartment, when the patient condition requires, two of the following personnel approved by the medical director as medical crew members:

(1) EMT-Paramedic;

(2) nurse practitioner;

(3) physician

(4) physician assistant;

(5) registered nurse; and

(6) respiratory therapist.

(b) When transporting patients that do not require specialty care transport skills or procedures, staffing for the vehicles used in the ground specialty care transport program shall be at a level to ensure compliance with G.S. 131E-158(a).

(c) In addition to the requirements of specialty care transport programs in Rule .0301 of this Section, ground programs providing specialty care transports shall document that the program has:

(1) a communication system that will provide two-way voice communications to medical crew members anywhere in the service area of the program. The medical director shall verify that the communications system is satisfactory for on-line medical direction;

(2) medical crew members that have all completed training regarding:

(A) operation of the EMS communications system used in the program; and

(B) the medical and safety equipment specific to the vehicles used in the program. This training shall be conducted every six months;

(3) operational protocols for the management of equipment, supplies and medications. These protocols shall include:

(A) a standard equipment and supply listing for all ambulance vehicles used in the program. This listing shall meet or exceed the requirements for each category of ambulance used in the program as found in Rules .0207, .0208, .0209, and .0210 of this Subchapter;

(B) a standard listing of medications for all ambulance and EMS nontransporting vehicles used in the system. This listing shall be based on the local treatment protocols and be approved by the medical director;

(C) a methodology to assure that each vehicle contains the required equipment and supplies on each response;

(D) a methodology for cleaning and maintaining the equipment and vehicles; and

(E) a methodology for assuring that supplies and medications are not used beyond the expiration date and stored in a temperature controlled atmosphere according to manufacturer's specifications;

(4) a written plan for providing emergency vehicle operation education for program personnel who operate emergency vehicles; and

(5) a written plan specifying how EMS Systems will request ambulances operated by the program.

(d) Ground Specialty Care Transport programs based outside of North Carolina may be granted approval by the OEMS to operate in North Carolina by submitting an application for program approval. The application shall document that the program meets all criteria specified in Rules .0204 and .0301 of this Subchapter and Paragraphs (a) and (b) of this Rule.

History Note: *Authority G.S. 143-508(d)(1), (d)(8), (d)(9);*
Temporary Adoption Eff. January 1, 2002;
Eff. April 1, 2003;
Amended Eff. January 1, 2004.

10A NCAC 13P .0304 HOSPITAL-AFFILIATED GROUND SPECIALTY CARE TRANSPORT PROGRAMS USED FOR INPATIENT TRANSPORTS

(a) Patients transported by Hospital-affiliated Ground Specialty Care Transport Program shall:

(1) Have a medical need for one or more of the skills or procedures as defined for Specialty Care Transport Programs as defined in .0301(a)(4); or

(2) Be a patient of the hospital administering the program, or be scheduled for admission to or discharged from the hospital administering the program;

(b) In addition to the general requirements of Specialty Care Transport Programs in Rule .0301 of this section, hospital-affiliated ground programs providing specialty care transports shall document that the program has:

(1) A communication system that will provide, at a minimum, two-way voice communications to medical crew members anywhere in the service area of the program. The medical director shall verify that the communications system is satisfactory for on-line medical direction.

(2) Medical crew members that have all completed training regarding:

(A) Operation of the EMS communications system used in the program; and

(B) The medical and safety equipment specific to the vehicles used in the program. This training shall be conducted every six months.

(3) Staffing at a level to ensure the capability to provide in the patient compartment, when the patient's condition requires, two of the following personnel approved by the medical director as medical crew members:

(A) EMT-Paramedic;

(B) Nurse practitioner;

(C) Physician;

(D) Physician assistant;

(E) Registered nurse; or

(F) Respiratory therapist.

(4) Operational protocols for the management of equipment, supplies, and medications. These protocols shall include:

(A) A standard equipment and supply listing for all ambulance vehicles used in the program. This listing shall meet or exceed the requirements for each category of ambulance used in the program as found in Rules .0207, .0208, .0209, and .0210 of this Subchapter;

(B) A standard listing of medications for all ambulance and EMS nontransporting vehicles used in the program. This listing shall be based on the local treatment protocols and be approved by the medical director;

(C) A methodology to assure that each vehicle contains the required equipment and supplies on each response

(D) A methodology for cleaning and maintaining the equipment and vehicles; and

(E) A methodology for assuring that supplies and medications are not used beyond the expiration date and stored in a temperature-controlled atmosphere according to manufacturer's specifications.

(5) A written plan for providing emergency vehicle operation education for program personnel who operate emergency vehicles.

(6) A written plan specifying how EMS systems will request ambulances operated by the program.

(c) Hospital-Affiliated Ground Specialty Care Transport Programs based outside of North Carolina may be granted approval by the OEMS to operate in North Carolina by submitting an application for program approval. The application

shall document that the program meets all criteria specified in Rules .0204 and .0301 of this Subchapter and Paragraphs (a) and (b) of this Rule.

History Note: *Authority G.S. 143-508(d)(1); (d)(8); (d)(9);*
Temporary Adoption Eff. January 1, 2002;
Eff. April 1, 2003.

SECTION .0400 -- MEDICAL OVERSIGHT

10A NCAC 13P .0401 COMPONENTS OF MEDICAL OVERSIGHT FOR EMS SYSTEMS

Each EMS System operating within the scope of practice for EMD, EMT-I, or EMT-P or seeking designation as a Model EMS System shall have the following components in place to assure medical oversight of the system:

(1) a medical director appointed, either directly or by documented delegation, by the county responsible for establishing the EMS System. Systems may elect to appoint one or more assistant medical directors.
   (a) For EMS Systems, the medical director and assistant medical directors shall meet the criteria as defined in the "North Carolina College of Emergency Physicians: Standards for Medical Oversight and Data Collection," incorporated by reference in accordance with G.S. 150B-21.6, including subsequent amendments and editions. This document is available from the OEMS, 2707 Mail Service Center, Raleigh, North Carolina 27699-2707, at no cost; and
   (b) For Model EMS Systems, the medical director and assistant medical directors shall also meet the additional criteria for medical directors of Model EMS Systems as defined in the "North Carolina College of Emergency Physicians: Standards for Medical Oversight and Data Collection," incorporated by reference in accordance with G.S. 150B-21.6, including subsequent amendments and editions. This document is available from the OEMS, 2707 Mail Service Center, Raleigh, North Carolina 27699-2707, at no cost;
(2) written treatment protocols for use by EMS personnel;
(3) for systems providing EMD service, an EMDPRS approved by the medical director;
(4) an EMS Peer Review Committee; and
(5) written procedures for use by EMS personnel to obtain on-line medical direction. On-line medical direction shall:
   (a) be restricted to medical orders that fall within the scope of practice of the EMS personnel and within the scope of approved system treatment protocols;
   (b) be provided only by a physician, MICN, EMS-NP, or EMS-PA. Only physicians may deviate from written treatment protocols; and
   (c) be provided by a system of two-way voice communication that can be maintained throughout the treatment and disposition of the patient.

History Note: *Authority G.S. 143-508(b); 143-509(12);*
Temporary Adoption Eff. January 1, 2002;
Eff. April 1, 2003;
Amended Eff. January 1, 2004.

10A NCAC 13P .0402 COMPONENTS OF MEDICAL OVERSIGHT FOR SPECIALTY CARE TRANSPORT PROGRAMS

Each Specialty Care Transport Program shall have the following components in place to assure Medical Oversight of the system:

(1) a medical director. The administration of the Specialty Care Transport Program shall appoint a medical director following the criteria for medical directors of Specialty Care Transport Programs as defined by the "North Carolina College of Emergency Physicians: Standards for Medical Oversight and Data Collection," incorporated by reference in accordance with G.S. 150B-21.6, including subsequent amendments and editions. This document is available from the OEMS, 2707 Mail Service Center, Raleigh, North Carolina 27699-2707, at no cost. The program administration may elect to appoint one or more assistant medical directors;
(2) treatment protocols for use by medical crew members;

(3) an EMS Peer Review Committee; and
(4) a written protocol for use by medical crew members to obtain on-line medical direction. On-line medical direction shall:
(a) be restricted to medical orders that fall within the scope of practice of the medical crew members and within the scope of approved program treatment protocols;
(b) be provided only by a physician, MICN, EMS-NP, or EMS-PA. Only physicians may deviate from written treatment protocols; and
(c) be provided by a system of two-way voice communication that can be maintained throughout the treatment and disposition of the patient.

History Note: *Authority G.S. 143-508(b); 143-509(12);*
Temporary Adoption Eff. January 1, 2002;
Eff. April 1, 2003;
Amended Eff. January 1, 2004.

10A NCAC 13P .0403 RESPONSIBILITIES OF THE MEDICAL DIRECTOR FOR EMS SYSTEMS

(a) The Medical Director for an EMS System shall be responsible for the following:
(1) ensure that medical control is available 24 hours a day;
(2) the establishment, approval and annual updating of treatment protocols;
(3) EMD programs, the establishment, approval, and annual updating of the EMDPRS;
(4) medical supervision of the selection, system orientation, continuing education and performance of EMS personnel;
(5) medical supervision of a scope of practice performance evaluation for all EMS personnel in the system based on the treatment protocols for the system;
(6) the medical review of the care provided to patients;
(7) providing guidance regarding decisions about the equipment, medical supplies, and medications that will be carried on ambulances or EMS nontransporting vehicles within the scope of practice of EMT-I or EMT-P; and
(8) keeping the care provided up to date with current medical practice.

(b) Any tasks related to Paragraph (a) of this Rule may be completed, through written delegation, by assisting physicians, physician assistants, nurse practitioners, registered nurses, EMD's, or EMT-P's.

(c) The Medical Director may suspend temporarily, pending due process review, any EMS personnel from further participation in the EMS System when it is determined the activities or medical care rendered by such personnel may be detrimental to the care of the patient, constitute unprofessional behavior, or result in non-compliance with credentialing requirements.

History Note: *Authority G.S. 143-508(b); 143-509(12);*
Temporary Adoption Eff. January 1, 2002;
Eff. April 1, 2003;
Amended Eff. January 1, 2004.

10A NCAC 13P .0404 RESPONSIBILITIES OF THE MEDICAL DIRECTOR FOR SPECIALTY CARE TRANSPORT PROGRAMS

(a) The medical director for a Specialty Care Transport Program shall be responsible for the following:
(1) The establishment, approval, and periodic updating of treatment protocols;
(2) Medical supervision of the selection, program orientation, continuing education, and performance of medical crew members;
(3) Medical supervision of a scope of practice performance evaluation for all medical crew members in the program based on the treatment protocols for the program;
(4) The medical review of the care provided to patients;
(5) Keeping the care provided up to date with current medical practice; and
(6) In air medical programs, determination and specification of the medical equipment required in Item (2) of Rule .0209 of this Subchapter that is carried on a mission based on anticipated patient care needs.

(b) Any tasks related to Paragraph (a) of this Rule may be completed, through clearly established written delegation, by assisting physicians, physician assistants, nurse practitioners, registered nurses, or medical crew members.

(c) The medical director shall have the authority to suspend temporarily, pending due process review, any medical crew members from further participation in the Specialty Care Transport Program when it is determined the activities or medical care rendered by such personnel may be detrimental to the care of the patient, constitute unprofessional behavior, or result in non-compliance with credentialing requirements.

History Note: *Authority G.S. 143-508(b); 143-509(12);*
Temporary Adoption Eff. January 1, 2002;
Eff. April 1, 2003.

10A NCAC 13P .0405 REQUIREMENTS FOR TREATMENT PROTOCOLS FOR EMS SYSTEMS

(a) Written Treatment Protocols:

(1) Used in EMS Systems shall meet the standard treatment protocols as defined in the "North Carolina College of Emergency Physicians: Standards for Medical Oversight and Data Collection," incorporated by reference in accordance with G.S. 150B-21.6, including subsequent amendments and editions. This document is available from the OEMS, 2707 Mail Service Center, Raleigh, North Carolina 27699-2707, at no cost;

(2) Used in Model EMS Systems shall also meet the standard treatment protocols for Model EMS Systems as defined in the "North Carolina College of Emergency Physicians: Standards for Medical Oversight and Data Collection," incorporated by reference in accordance with G.S. 150B-21.6, including subsequent amendments and editions. This document is available from the OEMS, 2707 Mail Service Center, Raleigh, North Carolina 27699-2707, at no cost; and

(3) Shall not contain medical procedures, medications, or intravenous fluids that exceed the scope of practice defined by the North Carolina Medical Board pursuant to G.S. 143-514 for the level of care offered in the EMS System and any other applicable health care licensing board.

(b) Treatment protocols developed locally shall meet the requirements of Paragraph (a) of this Rule, shall be reviewed annually and any change in the treatment protocols shall be submitted to the OEMS Medical Director for review and approval at least 30 days prior to the implementation of the change.

History Note: *Authority G.S. 143-508(b); 143-509(12);*
Temporary Adoption Eff. January 1, 2002;
Eff. April 1, 2003;
Amended Eff. January 1, 2004.

10A NCAC 13P .0406 REQUIREMENTS FOR TREATMENT PROTOCOLS FOR SPECIALTY CARE TRANSPORT PROGRAMS

(a) Treatment protocols used by medical crew members within a Specialty Care Transport Program shall:

(1) be approved by the OEMS Medical Director and incorporate all skills, medications, equipment, and supplies for Specialty Care Transport Programs as defined by the "North Carolina College of Emergency Physicians: Standards for Medical Oversight and Data Collection," incorporated by reference in accordance with G.S. 150B-21.6, including subsequent amendments and editions. This document is available from the OEMS, 2707 Mail Service Center, Raleigh, North Carolina 27699-2707, at no cost; and

(2) not contain medical procedures, medications, or intravenous fluids that exceed the scope of practice of the medical crew members.

(b) Treatment protocols shall be reviewed annually, and any change in the treatment protocols shall be submitted to the OEMS Medical Director for review and approval at least 30 days prior to the implementation of the change.

History Note: *Authority G.S. 143-508(b); 143-509(12);*
Temporary Adoption Eff. January 1, 2002;
Eff. April 1, 2003;
Amended Eff. January 1, 2004.

10A NCAC 13P .0407 REQUIREMENTS FOR EMERGENCY MEDICAL DISPATCH PRIORITY REFERENCE SYSTEM

(a) EMDPRS used by an EMD within an approved EMD program shall:

(1) be approved by the OEMS Medical Director and meet or exceed the statewide standard for EMDPRS as defined by the "North Carolina College of Emergency Physicians: Standards for Medical Oversight and Data Collection," incorporated by reference in accordance with G.S. 150B-21.6, including subsequent amendments and editions. This document is available from the OEMS, 2707 Mail Service Center, Raleigh, North Carolina 27699-2707, at no cost; and

(2) not exceed the EMD scope of practice defined by the North Carolina Medical Board pursuant to G.S. 143-514.

(b) An EMDPRS developed locally shall be reviewed and updated annually and submitted to the OEMS Medical Director for approval. Any change in the EMDPRS shall be submitted to the OEMS Medical Director for review and approval at least 30 days prior to the implementation of the change.

History Note: *Authority G.S. 143-508(b); 143-509(12);*
Temporary Adoption Eff. January 1, 2002;
Eff. April 1, 2003;
Amended Eff. January 1, 2004.

10A NCAC 13P .0408 EMS PEER REVIEW COMMITTEE FOR EMS SYSTEMS

(a) The EMS Peer Review Committee for an EMS System shall:

(1) be composed of membership as defined in G.S. 131E-155(6b).

(2) appoint a physician as chairperson;

(3) meet at least quarterly;

(4) analyze system data to evaluate the ongoing quality of patient care and medical direction within the system;

(5) use information gained from system data analysis to make recommendations regarding the content of continuing education programs for EMS personnel;

(6) review treatment protocols of the EMS System and make recommendations to the medical director for changes;

(7) establish a written procedure to guarantee reviews for EMS personnel temporarily suspended by the medical director; and

(8) maintain minutes of committee meetings throughout the approval period of the EMS System.

(b) The EMS Peer Review Committee shall adopt written guidelines that address:

(1) structure of committee membership;

(2) appointment of committee officers;

(3) appointment of committee members;

(4) length of terms of committee members;

(5) frequency of attendance of committee members;

(6) establishment of a quorum for conducting business; and

(7) confidentiality of medical records and personnel issues.

History Note: *Authority G.S. 143-508(b); 143-509(12);*
Temporary Adoption Eff. January 1, 2002;
Eff. April 1, 2003;
Amended Eff. January 1, 2004.

10A NCAC 13P .0409 EMS PEER REVIEW COMMITTEE FOR SPECIALTY CARE TRANSPORT PROGRAMS

(a) The EMS Peer Review Committee for a Specialty Care Transport Program shall:

(1) be composed of membership as defined in G.S. 131E-155(6b);

(2) appoint a physician as chairperson;

(3) meet at least quarterly;

(4) analyze program data to evaluate the ongoing quality of patient care and medical direction within the program;

(5) use information gained from program data analysis to make recommendations regarding the content of continuing education programs for medical crew members;

(6) review treatment protocols of the Specialty Care Transport Programs and make recommendations to the medical director for changes;
(7) establish a written procedure to guarantee reviews for medical crew members temporarily suspended by the medical director; and
(8) maintain minutes of committee meetings throughout the approval period of the Specialty Care Transport Program.

(b) Each EMS Peer Review Committee For Specialty Care Transport Programs shall adopt written guidelines that address:

(1) structure of committee membership;
(2) appointment of committee officers;
(3) appointment of committee members;
(4) length of terms of committee members;
(5) frequency of attendance of committee members;
(6) establishment of a quorum for conducting business; and
(7) confidentiality of medical records and personnel issues.

History Note: *Authority G.S. 143-508(b); 143-509(12);*
Temporary Adoption Eff. January 1, 2002;
Eff. April 1, 2003;
Amended Eff. January 1, 2004.

SECTION .0500 – EMS PERSONNEL

10A NCAC 13P .0501 EDUCATIONAL PROGRAMS

(a) An educational program approved to qualify credentialed EMS personnel to perform within their scope of practice shall be offered by an EMS educational institution.

(b) Educational programs approved to qualify EMS personnel for credentialing shall meet the educational objectives of the:

(1) "US DOT NHTSA First Responder: National Standard Curriculum" for MR personnel;
(2) "US DOT NHTSA EMT-Basic: National Standard Curriculum" for EMT personnel;
(3) "US DOT NHTSA EMT-Paramedic: National Standard Curriculum" for EMT-I and EMT-P personnel. For EMT-I personnel, the educational objectives shall be limited to the following:

(A) Module 1: Preparatory

SECTION	TITLE	LESSON OBJECTIVES
1-1	EMS Systems / Roles & Responsibilities	1-1.1 – 1-1.46
1-2	The Well Being of the Paramedic	1-2.1 – 1-2.46
1-4	Medical / Legal Issues	1-4.1 – 1-4.35
1-5	Ethics	1-5.1 – 1-5.11
1-6	General Principles of Pathophysiology	1-6.3; 1-6.5 –1-6.9; 1-6.13 –1-6.16; 1-6.19 – 1-6.25; 1-6.27 – 1-6.31
1-7	Pharmacology	1-7.1 – 1-7.31
1-8	Venous Access / Medication Administration	1-8.1 – 1-8.8; 1-8.10 – 1-8.17; 1-8.19 – 1-8.34; 1-8.36 – 1-8.38; 1-8.40 – 1-8.43
1-9	Therapeutic Communications	1-9.1 – 1-9.21

(B) Module 2: Airway

SECTION	TITLE	LESSON

		OBJECTIVES
2-1	Airway Management & Ventilation	2-1.1 – 2-1.10; 2-1.12 – 2-1.40; 2-1.42 – 2-1.64; 2-1.69; 2-1.73 – 2-1.89; 2-1.93 – 2-1.103; 2-1.104a-d; 2-1.105 – 2-1.106; 2-1.108

(C) Module 3: Patient Assessment

SECTION	TITLE	LESSON OBJECTIVES
3-2	Techniques of Physical Examination	3-2.1 – 3-2.88

(D) Module 4: Trauma

SECTION	TITLE	LESSON OBJECTIVES
4-2	Hemorrhage and Shock	4-2.1 – 4-2.54
4-4	Burns	4-4.25 – 4-4.30; 4-4.80 – 4-4.81

(E) Module 5: Medical

SECTION	TITLE	LESSON OBJECTIVES
5-1	Pulmonary	5-1.2 – 5-1.7; 5-1.10bcdefjk – 5-1.14
5-2	Cardiology	5-2.1 – 5-2.5; 5-2.8; 5-2.11 – 5-2.12; 5-2.14; 5-2.29 – 5-2.30; 5-2.53; 5-2.65 – 5-2.68; 5-2.70; 5-2.72 – 5-2.73; 5-2.75 – 5-2.77; 5-2.79 – 5-2.81; 5-2.84 – 5-2.89; 5-2.91 – 5-2.95; 5-2.121 – 5-2.125; 5-2.128 – 5-2.133; 5-2.150; 5-2.159; 5-2.162; 5-2.165; 5-2.168; 5-2.179 – 5-2.180; 5-2.184; 5-2.193 – 5-2.194; 5-2.201; 5-2.205ab; 5-2.206 – 5-2.207

5-3	Neurology	5-3.11 – 5-3.17; 5-3.82 – 5-3.83
5-4	Endocrinology	5-4.8 – 5-4.48
5-5	Allergies and Anaphylaxis	5-5.1 – 5-5.19
5-8	Toxicology	5-8.40 – 5-8.56; 5-8.62

(F) Module 7: Assessment Based Management

SECTION	TITLE	LESSON OBJECTIVES
7-1	Assessment Based Management	7-1.1 – 7-1.19 (objectives 7-1.12 and 7-1.19 should include only abefhklo)

(4) "US DOT NHTSA Emergency Medical Dispatcher: National Standard Curriculum" for EMD personnel; or
(5) "National Guidelines for Educating EMS Instructors" for EMS Instructors.

These documents are incorporated by reference in accordance with G.S. 150B-21.6, including subsequent amendments and additions. These documents are available from NHTSA, 400 7th Street, SW, Washington, D.C. 20590, at no cost.

(c) Educational programs approved to qualify EMS personnel for renewal of credentials shall follow the guidelines of the:

(1) "US DOT NHTSA First Responder Refresher: National Standard Curriculum" for MR personnel;
(2) "US DOT NHTSA EMT-Basic Refresher: National Standard Curriculum" for EMT personnel;
(3) "EMT-P and EMT-I Continuing Education National Guidelines" for EMT-I and EMT-P personnel; or
(4) "US DOT NHTSA Emergency Medical Dispatcher: National Standard Curriculum" for EMD personnel.

These documents are incorporated by reference in accordance with G.S. 150B-21.6, including subsequent amendments and additions. These documents are available from NHTSA, 400 7th Street, SW, Washington, D.C. 20590, at no cost.

History Note: *Authority G.S. 143-508(d)(3), (d)(4); 143-514;*
Temporary Adoption Eff. January 1, 2002;
Eff. January 1, 2004.

10A NCAC 13P .0502 INITIAL CREDENTIALING REQUIREMENTS FOR MR, EMT, EMT-I, EMT-P, AND EMD

(a) MR, EMT, EMT-I, EMT-P, and EMD applicants shall meet the following criteria within one year of the completion date of the approved educational program for their level of application:

(1) Be at least 18 years of age.
(2) Successfully complete a scope of practice performance evaluation based on the educational objectives in Rule .0501(b) of this Section consistent with their level of application and approved by the OEMS. This evaluation shall be conducted under the direction of the educational medical advisor or a Level II EMS Instructor credentialed at or above the level of application and designated by the educational medical advisor.
(3) Successfully complete a written examination administered by the OEMS or equivalent. Applicants who fail the written EMT examination but achieve a minimum score of 70% on the medical responder subset contained within the examination may be credentialed as medical responders. If the educational program was completed over one year prior to application, applicants shall submit evidence of completion of continuing education during the past year. This continuing education shall be based on the educational objectives in Rule .0501(c) of this Section consistent with their level of application and approved by the OEMS.

(b) EMD applicants shall successfully complete, within one year prior to application, an AHA CPR course or equivalent, including infant, child, and adult CPR, in addition to Subparagraph (a)(1), (a)(2), and (a)(3) of this Rule.

History Note: *Authority G.S. 131E-159 (a)(b); 143-508(d)(3);*
Temporary Adoption Eff. January 1, 2002;
Eff. February 1, 2004.

10A NCAC 13P .0503 TERM OF CREDENTIALS FOR EMS PERSONNEL
Credentials for EMS Personnel shall be valid for a period of four years.

History Note: *Authority G.S. 131E-159 (a);*
Temporary Adoption Eff. January 1, 2002;
Eff. April 1, 2003.

10A NCAC 13P .0504 RENEWAL OF CREDENTIALS FOR MR, EMT, EMT-I, EMT-P, AND EMD
MR, EMT, EMT-I, EMT-P, and EMD applicants shall renew credentials by presenting documentation to the OEMS that they have successfully completed:

(1) an approved educational program as described in Rule .0501(c) of this Section; and
(2) within one year prior to renewal, a scope of practice performance evaluation based on the educational objectives in Rule .0501(c) of this Section consistent with their level of application and approved by the OEMS. This evaluation shall be conducted under the direction of the educational medical advisor, EMS System medical director, Specialty Care Transport Program medical director, or a Level II EMS Instructor credentialed at or above the level of application and designated by the educational medical advisor, EMS System medical director, or Specialty Care Transport Program medical director.

History Note: *Authority G.S. 131-159(a); 143-508(d)(3);*
Temporary Adoption Eff. January 1, 2002;
Eff. February 1, 2004.

10A NCAC 13P .0505 SCOPE OF PRACTICE FOR EMS PERSONNEL
EMS Personnel educated in approved programs, credentialed by the OEMS, and affiliated with an approved EMS System may perform acts and administer intravenous fluids and medications as allowed by the North Carolina Medical Board pursuant to G.S. 143-514.

History Note: *Authority G.S. 143-508(d)(6); 143-514;*
Temporary Adoption Eff. January 1, 2002;
Eff. April 1, 2003.

10A NCAC 13P .0506 PRACTICE SETTINGS FOR EMS PERSONNEL
Credentialed EMS Personnel may function in the following practice settings in accordance with the protocols approved by the medical director of the EMS System or Specialty Care Transport Program with which they are affiliated, and by the OEMS:

(1) at the location of a physiological or psychological illness or injury including transportation to an appropriate treatment facility if required;
(2) at public or community health facilities in conjunction with public and community health initiatives;
(3) in hospitals and clinics;
(4) in residences, facilities, or other locations as part of wellness or injury prevention initiatives within the community and the public health system; and
(5) at mass gatherings or special events.

History Note: *Authority G.S. 143-508(d)(7);*
Temporary Adoption Eff. January 1, 2002;
Eff. April 1, 2003;
Amended Eff. January 1, 2004.

10A NCAC 13P .0507 CREDENTIALING REQUIREMENTS FOR LEVEL I EMS INSTRUCTORS
(a) Applicants for credentialing as a Level I EMS Instructor shall:

(1) be currently credentialed by the OEMS as an EMT, EMT-I, EMT-P, or EMD;
(2) have three years experience at the scope of practice for the level of application;
(3) within one year prior to application, successfully complete both a clinical and educational scope of practice performance evaluation based on the educational objectives in Rule .0501(b) of this Section consistent with their level of application and approved by the OEMS:
    (A) For a credential to teach at the EMT level, this evaluation shall be conducted under the direction of a Level II EMS Instructor credentialed at or above the level of application; and
    (B) For a credential to teach at the EMT-I or EMT-P levels, this evaluation shall be conducted under the direction of the educational medical advisor, a Level II EMS Instructor credentialed at or above the level of application and designated by the educational medical advisor;
    (C) For a credential to teach at the EMD level, this evaluation shall be conducted under the direction of the educational medical advisor or a Level I EMS Instructor credentialed at the EMD level designated by the educational medical advisor.
(4) have 100 hours of teaching experience in an approved EMS educational program or equivalent;
(5) successfully complete an educational program as described in Rule .0501(b)(5) of this Section;
(6) within one year prior to application, attend a Level I EMS Instructor workshop sponsored by the OEMS; and
(7) have a high school diploma or General Education Development certificate.

(b) The credential of a Level I EMS Instructor shall be valid for four years, unless any of the following occurs:
(1) the OEMS imposes an administrative action against the instructor credential; or
(2) the instructor fails to maintain a current EMT, EMT-I, EMT-P, or EMD credential at the highest level that the instructor is approved to teach.

History Note: *Authority G.S. 143-508(d)(3);*
Temporary Adoption Eff. January 1, 2002;
Eff. February 1, 2004.

10A NCAC 13P .0508 CREDENTIALING REQUIREMENTS FOR LEVEL II EMS INSTRUCTORS

(a) Applicants for credentialing as a Level II EMS Instructor shall:
(1) be currently credentialed by the OEMS as an EMT, EMT-I, EMT-P, or EMD;
(2) complete post-secondary level education equal to or exceeding an Associate Degree;
(3) within one year prior to application, successfully complete both a clinical and educational scope of practice performance evaluation based on the educational objectives in Rule .0501(b) of this Section consistent with their level of application and approved by the OEMS:
    (A) For a credential to teach at the EMT level, this evaluation shall be conducted under the direction of a Level II EMS Instructor credentialed at or above the level of application; and
    (B) For a credential to teach at the EMT-I or EMT-P level, this evaluation shall be conducted under the direction of the educational medical advisor, a Level II EMS Instructor credentialed at or above the level of application and designated by the educational medical advisor;
    (C) For a credential to teach at the EMD level, this evaluation shall be conducted under the direction of the educational medical advisor or a Level I EMS Instructor credentialed at the EMD level designated by the educational medical advisor.
(4) have two years teaching experience as a Level I EMS Instructor or equivalent;
(5) successfully complete the "EMS Education Administration Course" adopted by the North Carolina Community College System, incorporated by reference in accordance with G.S. 150B-21.6, including subsequent amendments and additions. This document is available from the North Carolina Community College System, 200 West Jones Street, Raleigh, North Carolina 27603, at no cost; and
(6) attend a Level II EMS Instructor workshop sponsored by the OEMS;

(b) The credential of a Level II EMS Instructor shall be valid for four years, unless any of the following occurs:
(1) The OEMS imposes an administrative action against the instructor credential; or
(2) The instructor fails to maintain a current EMT, EMT-I, EMT-P, or EMD credential at the highest level that the instructor is approved to teach.

History Note: *Authority G.S. 143-508(d)(3);*
Temporary Adoption Eff. January 1, 2002;
Eff. February 1, 2004.

10A NCAC 13P .0509 CREDENTIALING OF INDIVIDUALS TO ADMINISTER LIFESAVING TREATMENT TO PERSONS SUFFERING AN ADVERSE REACTION TO AGENTS THAT MIGHT CAUSE ANAPHYLAXIS

(a) To become credentialed by the North Carolina Medical Care Commission to administer epinephrine to persons who suffer adverse reactions to agents that might cause anaphylaxis, a person shall meet the following:

(1) Be 18 years of age or older; and

(2) successfully complete an educational program taught by a physician licensed to practice medicine in North Carolina or designee of the physician. The educational program shall instruct individuals in the appropriate use of procedures for the administration of epinephrine to pediatric and adult victims who suffer adverse reactions to agents that might cause anaphylaxis and shall include at a minimum the following:

(A) definition of anaphylaxis;

(B) agents that might cause anaphylaxis and the distinction between them, including drugs, insects, foods, and inhalants;

(C) recognition of symptoms of anaphylaxis for both pediatric and adult victims;

(D) appropriate emergency treatment of anaphylaxis as a result of agents that might cause anaphylaxis;

(E) availability and design of packages containing equipment for administering epinephrine to victims suffering from anaphylaxis as a result of agents that might cause anaphylaxis;

(F) pharmacology of epinephrine including indications, contraindications, and side effects;

(G) discussion of legal implications of rendering aid; and

(H) instruction that treatment is to be utilized only in the absence of the availability of physicians or other practitioners who are authorized to administer the treatment.

(b) A credential to administer epinephrine to persons who suffer adverse reactions to agents that might cause anaphylaxis may be issued by the North Carolina Medical Care Commission upon receipt of a completed application signed by the applicant and the physician who taught or was responsible for the educational program. Applications may be obtained from the OEMS, 2707 Mail Service Center, Raleigh, North Carolina 27699-2707. All credentials shall be valid for a period of four years.

History Note: *Authority G.S. 143-508(d)(11); 143-509(9);*
Temporary Adoption Eff. January 1, 2003; January 1, 2002;
Eff. April 1, 2003;
Amended Eff. February 1, 2004.

10A NCAC 13P .0510 RENEWAL OF CREDENTIALS FOR LEVEL I AND LEVEL II EMS INSTRUCTORS

(a) Level I and Level II EMS Instructor applicants shall renew credentials by presenting documentation to the OEMS that they:

(1) are currently credentialed by the OEMS as an EMT, EMT-I, or EMT-P, or EMD;

(2) successfully completed, within one year prior to application, both a clinical and educational scope of practice performance evaluation based on the educational objectives in Rule .0501(b) of this Subchapter consistent with their level of application and approved by the OEMS:

(A) To renew a credential to teach at the EMT level, this evaluation shall be conducted under the direction of a Level II EMS Instructor credentialed at or above the level of application;

(B) To renew a credential to teach at the EMT-I or EMT-P level, this evaluation shall be conducted under the direction of the educational medical advisor, a Level II EMS Instructor credentialed at or above the level of application and designated by the educational medical advisor; and

(C) To renew a credential to teach at the EMD level, this evaluation shall be conducted under the direction of the educational medical advisor or a Level I EMS Instructor credentialed at the EMD level designated by the educational medical advisor.

(3) completed 96 hours of EMS instruction at the level of application; and
(4) completed 40 hours of educational professional development.

(b) The credential of a Level I or Level II EMS Instructor shall be valid for four years, unless any of the following occurs:

(1) the OEMS imposes an administrative action against the instructor credential; or
(2) the instructor fails to maintain a current EMT, EMT-I, EMT-P, or EMD credential at the highest level that the instructor is approved to teach.

History Note: *Authority G.S. 131E-159(a)(b); 143-508(d)(3);*
Eff. February 1, 2004.

SECTION .0600 – EMS EDUCATIONAL INSTITUTIONS

10A NCAC 13P .0601 CONTINUING EDUCATION EMS EDUCATIONAL INSTITUTION REQUIREMENTS

(a) Continuing Education EMS Educational Institutions shall be credentialed by the OEMS to provide EMS continuing education programs.

(b) Continuing Education EMS Educational Institutions shall have:

(1) at least a Level I EMS Instructor as program coordinator. The program coordinator shall hold a Level I EMS Instructor credential at a level equal to or greater than the highest level of continuing education program offered in the EMS System or Specialty Care Transport Program;
(2) a continuing education program consistent with the EMS System or Specialty Care Transport Program continuing education plan for EMS personnel;
    (A) In an EMS System, the continuing education programs for EMD, EMT-I, and EMT-P shall be reviewed and approved by the medical director of the EMS System.
    (B) In a Model EMS System, the continuing education program shall be reviewed and approved by the system continuing education coordinator and medical director.
    (C) In a Specialty Care Transport Program, the continuing education program shall be reviewed and approved by Specialty Care Transport Program Continuing Education Coordinator and the medical director.
(3) access to instructional supplies and equipment necessary for students to complete educational programs as defined in Rule .0501(c) of this Subchapter;
(4) educational programs offered in accordance with Rule .0501(c) of this Subchapter;
(5) an Educational Medical Advisor if offering educational programs that have not been reviewed and approved by a medical director of an EMS System or Specialty Care Transport Program. The Educational Medical Advisor shall meet the criteria as defined in the "North Carolina College of Emergency Physicians: Standards for Medical Oversight and Data Collection," incorporated by reference in accordance with G.S. 150B-21.6, including subsequent amendments and editions. This document is available from the OEMS, 2707 Mail Service Center, Raleigh, North Carolina 27699-2707, at no cost; and
(6) a written educational plan describing the delivery of educational programs, the record-keeping system detailing student attendance and performance, and the selection and monitoring of EMS instructors.

(c) An application for credentialing as a Continuing Education EMS Educational Institution shall be submitted to the OEMS for review. The application shall demonstrate that the applicant meets the requirements in Paragraph (b) of this Rule.

(d) Continuing Education EMS Educational Institution credentials shall be valid for a period of four years.

(e) It is not necessary for Continuing Education EMS Educational Institutions designated as the primary educational delivery agency for a Model EMS System to submit an application for renewal of credentials.

History Note: *Authority G.S. 143-508(d)(4), (13);*
Temporary Adoption Eff. January 1, 2002;
Eff. January 1, 2004.

10A NCAC 13P .0602 BASIC EMS EDUCATIONAL INSTITUTION REQUIREMENTS

(a) Basic EMS Educational Institutions may offer MR, EMT, and EMD courses for which they have been credentialed by the OEMS.
(b) For initial courses, Basic EMS Educational Institutions shall have:

(1) at least a Level I EMS Instructor as lead course instructor for MR and EMT courses. The lead course instructor must be credentialed at a level equal to or higher than the course offered;
(2) at least a Level I EMS Instructor credentialed at the EMD level as lead course instructor for EMD courses;
(3) a lead EMS educational program coordinator. This individual may be either a Level II EMS Instructor credentialed at or above the highest level of course offered by the institution, or a combination of staff who cumulatively meet the requirements of the Level II EMS Instructor referenced in this Paragraph. These individuals may share the responsibilities of the lead EMS educational coordinator. The details of this option shall be defined in the educational plan required in Subparagraph (b)(5) of this Rule. Basic EMS Educational Institutions offering only EMD courses may meet this requirement with a Level I EMS Instructor credentialed at the EMD level;
(4) an Educational Medical Advisor that meets the criteria as defined in the "North Carolina College of Emergency Physicians: Standards for Medical Oversight and Data Collection" incorporated by reference in accordance with G.S. 150B-21.6, including subsequent amendments and editions. This document is available from the OEMS, 2707 Mail Service Center, Raleigh, North Carolina 27699-2707, at no cost;
(5) a written educational plan describing the delivery of educational programs, the record-keeping system detailing student attendance and performance; and the selection and monitoring of EMS instructors; and
(6) access to instructional supplies and equipment necessary for students to complete educational programs as defined in Rule .0501(c) of this Subchapter.

(c) For EMS continuing education programs, Basic EMS Educational Institutions shall meet the requirements defined in Paragraphs (a) and (b) of Rule .0601 of this Section.
(d) An application for credentialing as a Basic EMS Educational Institution shall be submitted to the OEMS for review. The proposal shall demonstrate that the applicant meets the requirements in Paragraphs (b) and (c) of this Rule.
(e) Basic EMS Educational Institution credentials shall be valid for a period of four years.
(f) It is not necessary for Basic EMS Educational Institutions designated as the primary educational delivery agency for a Model EMS System to submit an application for renewal of credentials.

History Note: *Authority G.S. 143-508(d)(4), (13);*
Temporary Adoption Eff. January 1, 2002;
Eff. January 1, 2004.

10A NCAC 13P .0603 ADVANCED EMS EDUCATIONAL INSTITUTION REQUIREMENTS

(a) Advanced EMS Educational Institutions may offer all EMS educational programs for which they have been credentialed by the OEMS.
(b) For initial courses, Advanced EMS Educational Institutions shall have:

(1) at least a Level I EMS Instructor as lead course instructor for MR and EMT courses. The lead course instructor must be credentialed at a level equal to or higher than the course offered;
(2) at least a Level I EMS Instructor credentialed at the EMD level as lead course instructor for EMD courses;
(3) a Level II EMS Instructor as lead instructor for EMT-I and EMT-P courses. The lead course instructor must be credentialed at a level equal to or higher than the course offered;
(4) a lead EMS educational program coordinator. This individual may be either a Level II EMS Instructor credentialed at or above the highest level of course offered by the institution, or a combination of staff who cumulatively meet the requirements of the Level II EMS Instructor referenced in this Paragraph. These individuals may share the responsibilities of the lead EMS educational coordinator. The details of this option shall be defined in the educational plan required in Subparagraph (b)(6) of this Rule;
(5) an Educational Medical Advisor that meets the criteria as defined in the “North Carolina College of Emergency Physicians: Standards for Medical Oversight and Data Collection,” incorporated by reference in accordance with G.S. 150B-21.6, including subsequent amendments and editions. This

document is available from the OEMS, 2707 Mail Service Center, Raleigh, North Carolina 27699-2707, at no cost; and

(6) a written educational plan describing the delivery of educational programs, the record-keeping system detailing student attendance and performance; and the selection and monitoring of EMS instructors;

(7) access to instructional supplies and equipment necessary for students to complete educational programs as defined in Rule .0501(c) of this Subchapter.

(c) For EMS continuing education programs, Advanced EMS Educational Institutions shall meet the requirements defined in Paragraphs (a) and (b) of Rule .0601 of this Section.

(d) An application for credentialing as an Advanced EMS Educational Institution shall be submitted to the OEMS for review. The application shall demonstrate that the applicant meets the requirements in Paragraphs (b) and (c) of this Rule.

(e) Advanced Educational Institution credentials shall be valid for a period of four years.

(f) It is not necessary for Advanced EMS Educational Institutions designated as the primary educational delivery agency for a Model EMS System to submit an application for renewal of credentials.

History Note: *Authority G.S. 143-508(d)(4), (13);*
Temporary Adoption Eff. January 1, 2002;
Eff. February 1, 2004.

10A NCAC 13P .0604 TRANSITION FOR APPROVED TEACHING INSTITUTIONS

History Note: *Authority G.S. 143-508(b);*
Temporary Adoption Eff. January 1, 2002;
Eff. April 1, 2003;
Repealed Eff. January 1, 2004.

SECTION .0700 – ENFORCEMENT

10A NCAC 13P .0701 DENIAL, SUSPENSION, AMENDMENT OR REVOCATION

(a) The Department may deny, suspend, or revoke the permit of an ambulance or EMS nontransporting vehicle if the EMS provider:

(1) fails to substantially comply with the requirements of Section .0200 of this Subchapter;

(2) obtains or attempts to obtain a permit through fraud or misrepresentation; or

(3) fails to provide emergency medical care within the defined EMS service area in a timely manner.

(b) In lieu of suspension or revocation, the Department may issue a temporary permit for an ambulance or EMS nontransporting vehicle whenever the Department finds that:

(1) the EMS provider to which that vehicle is assigned has substantially failed to comply with the provisions of G.S. 131E, Article 7, and the rules adopted under that Article;

(2) there is a reasonable probability that the EMS provider can remedy the permit deficiencies within a length of time determined by the department; and

(3) there is a reasonable probability that the EMS provider will be willing and able to remain in compliance with the rules regarding vehicle permits for the foreseeable future.

(c) The Department shall give the EMS provider written notice of the temporary permit. This notice shall be given personally or by certified mail and shall set forth:

(1) the duration of the temporary permit not to exceed 60 days;

(2) a copy of the vehicle inspection form;

(3) the statutes or rules alleged to be violated; and

(4) notice to the EMS provider's right to a contested case hearing on the temporary permit.

(d) The temporary permit shall be effective immediately upon its receipt by the EMS provider and shall remain in effect until the earlier of the expiration date of the permit or until the Department:

(1) restores the vehicle to full permitted status; or

(2) suspends or revokes the vehicle permit.

(e) The Department may deny, suspend, or revoke the credentials of EMS personnel for any of the following reasons:

(1) failure to comply with the applicable performance and credentialing requirements as found in this Subchapter;

(2) making false statements or representations to the OEMS or willfully concealing information in connection with an application for credentials;
(3) being unable to perform as credentialed EMS personnel with reasonable skill and safety to patients and the public by reason of illness, use of alcohol, drugs, chemicals, or any other type of material or by reason of any physical or mental abnormality;
(4) unprofessional conduct, including but not limited to a failure to comply with the rules relating to the proper function of credentialed EMS personnel contained in this Subchapter or the performance of or attempt to perform a procedure that is detrimental to the health and safety of any person or that is beyond the scope of practice of credentialed EMS personnel or EMS instructors;
(5) conviction in any court of a crime involving moral turpitude, a conviction of a felony, or conviction of a crime involving the scope of practice of credentialed EMS personnel;
(6) by false representations obtaining or attempting to obtain money or anything of value from a patient;
(7) adjudication of mental incompetence;
(8) lack of competence to practice with a reasonable degree of skill and safety for patients including but not limited to a failure to perform a prescribed procedure, failure to perform a prescribed procedure competently or performance of a procedure that is not within the scope of practice of credentialed EMS personnel or EMS instructors;
(9) making false statements or representations, willfully concealing information, or failing to respond within a reasonable period of time and in a reasonable manner to inquiries from the OEMS;
(10) testing positive for any substance, legal or illegal, that is likely to impair the physical or psychological ability of the credentialed EMS personnel to perform all required or expected functions while on duty;
(11) representing or allowing others to represent that the credentialed EMS personnel has a credential that the credentialed EMS personnel does not in fact have; or
(12) failure to comply with G.S. 143-518 regarding the use or disclosure of records or data associated with EMS Systems, Specialty Care Transport Programs, or patients.

(f) The Department may amend any EMS provider license by reducing it from a full license to a provisional license whenever the Department finds that:

(1) the licensee has substantially failed to comply with the provisions of G.S. 131E, Article 7, and the rules adopted under that article;
(2) there is a reasonable probability that the licensee can remedy the licensure deficiencies within a reasonable length of time; and
(3) there is a reasonable probability that the licensee will be able thereafter to remain in compliance with the licensure rules for the foreseeable future.

(g) The Department shall give the licensee written notice of the amendment to the EMS provider license. This notice shall be given personally or by certified mail and shall set forth:

(1) the length of the provisional EMS provider license;
(2) the factual allegations;
(3) the statutes or rules alleged to be violated; and
(4) notice to the EMS provider's right to a contested case hearing on the amendment of the EMS provider license.

(h) The provisional EMS provider license shall be effective immediately upon its receipt by the licensee and shall be posted in a prominent location at the primary business location of the EMS provider, accessible to public view, in lieu of the full license. The provisional license shall remain in effect until the Department:

(1) restores the licensee to full licensure status; or
(2) revokes the licensee's license.

(i) The Department may revoke or suspend an EMS provider license whenever the Department finds that the licensee:

(1) has substantially failed to comply with the provisions of G.S. 131E, Article 7, and the rules adopted under that article and it is not reasonably probable that the licensee can remedy the licensure deficiencies within a reasonable length of time;
(2) has substantially failed to comply with the provisions of G.S. 131E, Article 7, and the rules adopted under that article and, although the licensee may be able to remedy the deficiencies within a reasonable period of time, it is not reasonably probable that the licensee will be able to remain in compliance with licensure rules for the foreseeable future;
(3) has failed to comply with the provision of G.S. 131E, Article 7, and the rules adopted under that article that endanger the health, safety or welfare of the patients cared for or transported by the licensee; or

(4) obtained or attempted to obtain an ambulance permit, EMS nontransporting vehicle permit, or EMS provider license through fraud or misrepresentation.

(j) The issuance of a provisional EMS provider license is not a procedural prerequisite to the revocation or suspension of a license pursuant to Paragraph (i) of this Rule.

(k) The Department may amend, deny, suspend, or revoke the credential of an EMS educational institution for any of the following reasons:

(1) failure to substantially comply with the requirements of Section .0600 of this Subchapter; or

(2) obtaining or attempting to obtain a credential through fraud or misrepresentation.

(l) The Department may amend, deny, suspend, or revoke the approval of an EMS System or designation of a Model EMS System for any of the following reasons:

(1) failure to substantially comply with the requirements of Section .0200 of this Subchapter; or

(2) obtaining or attempting to obtain designation through fraud or misrepresentation.

(m) The Department may amend, deny, suspend, or revoke the designation of a Specialty Care Transport Program for any of the following reasons:

(1) failure to substantially comply with the requirements of Section .0300 of this Subchapter; or

(2) obtaining or attempting to obtain designation through fraud or misrepresentation.

History Note: *Authority G.S. 131E-155.1(d); 131E-157(c); 131E-159(a); 143-508(d)(10);*
Temporary Adoption Eff. January 1, 2002;
Eff. January 1, 2004.

10A NCAC 13P .0702 PROCEDURES FOR DENIAL, SUSPENSION, AMENDMENT, OR REVOCATION

Denial, suspension, amendment or revocation of credentials, licenses, permits, approvals, or designations shall follow the law regarding contested cases found in G.S. 150B.

History Note: *Authority G.S. 143-508(d)(10);*
Temporary Adoption Eff. January 1, 2002;
Eff. April 1, 2003.

SECTION .0800 – TRAUMA SYSTEM DEFINITIONS

10A NCAC 13P .0801 TRAUMA SYSTEM DEFINITIONS

The following definitions apply throughout this Subchapter:

(1) "ACS" stands for the American College of Surgeons.

(2) "Advanced Trauma Life Support (ATLS)" refers to the course sponsored by the American College of Surgeons.

(3) "Affiliated Hospital" means a non-trauma center hospital that is owned by the trauma center such that a contract or other agreement exists between these facilities to allow for the diversion or transfer of the trauma center's patient population to this non-trauma center hospital.

(4) "Attending" is a physician who has completed medical or surgical residency and is either eligible to take boards in a specialty area or is boarded in a specialty.

(5) "Board Certified, Board Certification, Board Eligible, Board Prepared, or Boarded" means approval by the American Board of Medical Specialties, the Advisory Board for Osteopathic Specialties, or the Royal College of Physicians and Surgeons of Canada unless a further sub-specialty such as the American Board of Surgery or Emergency Medicine is specified.

(6) "Bypass" means the transport of an emergency medical services patient past an emergency medical services receiving facility for the purposes of accessing a designated trauma center or a higher-level trauma center.

(7) "Contingencies" are conditions placed on a trauma center's designation that, if unmet, can result in the loss or amendment of a hospital's designation.

(8) "Deficiency" is the failure to meet essential criteria for a trauma center's designation as specified in Section .0900 of this Subchapter, that can serve as the basis for a focused review or denial of a trauma center designation.

(9) "Department" means the North Carolina Department of Health and Human Services.

(10) "Diversion" means that a hospital of its own volition reroutes a trauma patient to a trauma center from the scene or referring hospital.

(11) "E-Code" is a numeric identifier that defines the cause of injury, taken from the International Classification of Diseases (ICD).

(12) "Essential Criteria" means those items listed in Rules .0901, .0902, and .0903 of this Section that are the minimum requirements in staffing, equipment, services, etc., for the respective level of trauma center designation (I, II, or III).

(13) "Focused Review" is an evaluation of the trauma center's corrective actions to remove contingencies (as the result of deficiencies) placed upon it following a renewal site visit.

(14) "Hospital" means a licensed facility as defined in G.S. 131E-176.

(15) "Immediately Available" means the physical presence of the health professional in a location in the trauma center as defined by the needs of the trauma patient.

(16) "Lead RAC Agency" is the agency (comprised of one or more Level I or II trauma centers) that provides staff support and serves as the coordinating entity for trauma planning in a region.

(17) "Level I Trauma Center" is a regional resource trauma center that has the capability of providing leadership, research, and total care for every aspect of injury from prevention to rehabilitation.

(18) "Level II Trauma Center" is a hospital that provides definitive trauma care regardless of the severity of the injury but may not be able to provide the same comprehensive care as a Level I trauma center and does not have trauma research as a primary objective.

(19) "Level III Trauma Center" is a hospital that provides prompt assessment, resuscitation, emergency operations, and stabilization, and arranges for hospital transfer as needed to a Level I or II trauma center.

(20) "Mid-level Practitioner means a physician assistant or nurse practitioner who routinely cares for trauma patients."

(21) "OEMS" means the Office of Emergency Medical Services.

(22) "Post Graduate Year Four (PGY4)" means any surgery resident having completed three clinical years of general surgical training. A pure laboratory year shall not constitute a clinical year.

(23) "Promptly Available" means the physical presence of health professionals in a location in the trauma center within a short period of time, that is defined by the trauma system (director) and continuously monitored by the performance improvement program.

(24) "RAC" stands for "Regional Advisory Committee" which is comprised of a lead RAC agency and a group representing trauma care providers and the community, for the purpose of regional trauma planning, establishing, and maintaining a coordinated trauma system.

(25) "Revocation" means the removal of a trauma center designation for concerns related to patient morbidity or mortality or failure to meet essential criteria or recurrent contingencies.

(26) "RFP" stands for "Request for Proposal" and is a standardized state document that must be completed by each hospital seeking initial or renewal trauma center designation.

(27) "Transfer Agreement" means a formal written agreement between two agencies specifying the appropriate transfer of patient populations delineating the conditions and methods of transfer.

(28) "Trauma Center" is a hospital facility designated by the State of North Carolina and distinguished by its ability to immediately manage, on a 24-hour basis, the severely injured patient or those at risk for severe injury.

(29) "Trauma Center Criteria" means essential criteria to define Level I, II, or III trauma centers.

(30) "Trauma Center Designation" means a formalized process of approval in which a hospital voluntarily seeks to have its trauma care capabilities and performance evaluated by experienced on-site reviewers.

(31) "Trauma Guidelines" are suggested standards for practice in a variety of situations within the trauma system.

(32) "Trauma Minimum Data Set" means the basic data required of all hospitals for submission to the trauma statewide database.

(33) "Trauma Patient" is any patient with an ICD-9-CM discharge diagnosis 800.00-959.9 excluding 905-909 (late effects of injury), 910.0-924 (blisters, contusions, abrasions, and insect bites), and 930-939 (foreign bodies).

(34) "Trauma Performance Improvement Program (TPIP)" means a system in which outcome data is used to modify the process of patient care and prevent repetition of adverse events.

(35) "Trauma Program" means an administrative entity that includes the trauma service and coordinates other trauma related activities. It must also include, at a minimum, the trauma medical director, trauma program manager/trauma coordinator, and trauma registrar. This program's reporting structure shall give it the ability to interact with at least equal authority with other departments providing patient care.

(36) "Trauma Protocols" are standards for practice in a variety of situations within the trauma system.

(37) "Trauma Registry" is an OEMS-maintained database to provide information for analysis and evaluation of the quality of patient care, including epidemiological and demographic characteristics of trauma patients.

(38) "Trauma Service" means a clinical service established by the medical staff that has oversight of and responsibility for the care of the trauma patient.

(39) "Trauma System" means an integrated network that ensures that acutely injured patients are expeditiously taken to hospitals appropriate for their level of injury.

(40) "Trauma Team" means a group of health care professionals organized to provide coordinated and timely care to the trauma patient.

(41) "Triage" is a predetermined schematic for patient distribution based upon established medical needs.

History Note: *Authority G.S. 131E-162;*
Temporary Adoption Eff. January 1, 2002;
Eff. April 1, 2003.

SECTION .0900 – TRAUMA CENTER STANDARDS AND APPROVAL

10A NCAC 13P .0901 LEVEL I TRAUMA CENTER CRITERIA

To receive designation as a Level I Trauma Center, a hospital shall have the following:

(1) A trauma program and a trauma service that have been operational for at least six months prior to application for designation;

(2) Membership in and inclusion of all trauma patient records in the North Carolina Trauma Registry for at least six months prior to submitting a Request for Proposal;

(3) Trauma medical director who is a board-certified general surgeon. The trauma medical director must:

- (a) Have a minimum of three years clinical experience on a trauma service or trauma fellowship training;
- (b) Serve on the center's trauma service;
- (c) Participate in providing care to patients with life-threatening or urgent injuries;
- (d) Participate in the North Carolina Chapter of the ACS Committee on Trauma as well as other regional and national trauma organizations;
- (e) Remain a current provider in the ACS' Advanced Trauma Life Support Course and in the provision of trauma-related instruction to other health care personnel; and
- (f) Be involved with trauma research and the publication of results and presentations.

(4) A full-time trauma nurse coordinator (TNC)/program manager (TPM) who is a registered nurse, licensed by the North Carolina Board of Nursing;

(5) A full-time trauma registrar (TR) who has a working knowledge of medical terminology, is able to operate a personal computer, and has demonstrated the ability to extract data from the medical record;

(6) A hospital department/division/section for general surgery, neurological surgery, emergency medicine, anesthesiology, and orthopaedic surgery, with designated chair or physician liaison to the trauma program for each;

(7) Clinical capabilities in general surgery with two separate posted call schedules. One shall be for trauma, one for general surgery. In those instances where a physician may simultaneously be listed on both schedules, there must be a defined back-up surgeon listed on the schedule to allow the trauma surgeon to provide care for the trauma patient. The trauma service director shall specify, in writing, the specific credentials that each back-up surgeon must have. These must state that the back-up surgeon has surgical privileges at the trauma center and is boarded or eligible in general surgery (with board certification in general surgery within five years of completing residency). If a trauma surgeon is simultaneously on call at more than one hospital, there shall be a defined, posted trauma surgery back-up call schedule composed of surgeons credentialed to serve on the trauma panel.

(8) Response of a trauma team to provide evaluation and treatment of a trauma patient 24 hours per day that includes:

(a) An in-house Post Graduate Year 4 (PGY4) or senior general surgical resident, at a minimum, who is a member of that hospital's surgical residency program and responds within 20 minutes of notification;

(b) A trauma attending whose presence at the patient's bedside within 20 minutes of notification is documented and who participates in therapeutic decisions and is present at all operative procedures;

(c) An emergency physician who is present in the Emergency Department 24 hours per day who is either board-certified or prepared in emergency medicine (by the American Board of Emergency Medicine or the American Osteopathic Board of Emergency Medicine). Emergency physicians caring only for pediatric patients may, as an alternative, be boarded or prepared in pediatric emergency medicine. Emergency physicians must be board-certified within five years after successful completion of a residency in emergency medicine and serve as a designated member of the trauma team until the arrival of the trauma surgeon;

(d) Neurosurgery specialists who are never simultaneously on-call at another Level II or higher trauma center, who are promptly available, if requested by the trauma team leader, unless there is either an in-house attending neurosurgeon, a Post Graduate Year 2 (PGY2) or higher in-house neurosurgery resident or an in-house trauma surgeon or emergency physician as long as the institution can document management guidelines and annual continuing medical education for neurosurgical emergencies. There must be a specified written back-up on the call schedule whenever the neurosurgeon is simultaneously on-call at a hospital other than the trauma center;

(e) Orthopaedic surgery specialists who are never simultaneously on-call at another Level II or higher trauma center, who are promptly available, if requested by the trauma team leader, unless there is either an in-house attending orthopaedic surgeon, a Post Graduate Year 2 (PGY2) or higher in-house orthopaedic surgery resident or an in-house trauma surgeon or emergency physician as long as the institution can document management guidelines and annual continuing medical education for orthopaedic emergencies. There must be a specified written back-up on the call schedule whenever the orthopaedist is simultaneously on-call at a hospital other than the trauma center;

(f) An in-house anesthesiologist or a Clinical Anesthesiology Year 3 (CA3) resident as long as an anesthesiologist on-call is advised and promptly available if requested by the trauma team leader, and

(g) Registered nursing personnel trained in the care of trauma patients.

(9) A written credentialing process established by the Department of Surgery to approve mid-level practitioners and attending general surgeons covering the trauma service. The surgeons must have board certification in general surgery within five years of completing residency;

(10) Neurosurgeons and orthopaedists serving the trauma service who are currently board certified or eligible. Those who are eligible must be board certified within five years after successful completion of the residency;

(11) Standard written protocols relating to trauma management formulated and routinely updated;

(12) Criteria to ensure team activation prior to arrival of trauma/burn patients to include the following:

(a) Shock;

(b) Respiratory distress;

(c) Airway compromise;

(d) Unresponsiveness (Glasgow Coma Scale less than 8) with potential for multiple injuries; and

(e) Gunshot wound to head, neck, or torso.

(13) Surgical evaluation, based upon the following criteria, by the health professional who is promptly available:

(a) Proximal amputations;

(b) Burns meeting institutional transfer criteria;

(c) Vascular compromise;

(d) Crush to chest or pelvis;

(e) Two or more proximal long bone fractures; and

(f) Spinal cord injury.

(14) Surgical consults, based upon the following criteria, by the health professional who is promptly available:

(a) Falls greater than 20 feet;

(b) Pedestrian struck by motor vehicle;

(c) Motor vehicle crash with:

(i) Ejection (includes motorcycle);

(ii) Rollover;

(iii) Speed greater than 40 mph; or

(iv) Death of another individual at the scene;

(d) Extremes of age, less than five or greater than 70 years;

(15) Clinical capabilities (promptly available if requested by the trauma team leader, with a posted on-call schedule), to include individuals credentialed in the following:

(a) Cardiac surgery;

(b) Critical care;

(c) Hand surgery;

(d) Microvascular/replant surgery;

(e) Neurosurgery (The neurosurgeon must be dedicated to one hospital or a back-up call schedule must be available. If fewer than 25 emergency neurosurgical trauma operations are done in a year, and the neurosurgeon is dedicated only to that hospital, then a published back-up call list is not necessary.)

(f) Obstetrics/gynecologic surgery;

(g) Opthalmic surgery;

(h) Oral/maxillofacial surgery;

(i) Orthopaedics (dedicated to one hospital or a back-up call schedule must be available);

(j) Pediatric surgery;

(k) Plastic surgery;

(l) Radiology;

(m) Thoracic surgery; and

(n) Urologic surgery.

(16) An Emergency Department that has:

(a) A designated physician director who is board-certified or prepared in emergency medicine (by the American Board of Emergency Medicine or the American Osteopathic Board of Emergency Medicine);

(b) 24-hour-per-day staffing by physicians physically present in the Emergency Department such that:

(i) At least one physician on every shift in the Emergency Department is either board-certified or prepared in emergency medicine (by the American Board of Emergency Medicine or the American Osteopathic Board of Emergency Medicine) to serve as the designated member of the trauma team at least until the arrival of the trauma surgeon. Emergency physicians caring only for pediatric patients may, as an alternative, be boarded in pediatric emergency medicine. All emergency physicians must be board-certified within five years after successful completion of the residency;

(ii) All remaining emergency physicians, if not board-certified or prepared in emergency medicine as outlined in Item (16)(b)(i) of this Rule, are board-certified, or eligible by the American Board of Surgery, American Board of Family Practice, or American Board of Internal Medicine, with each being board-certified within five years after successful completion of a residency; and

(iii) All emergency physicians practice emergency medicine as their primary specialty.

(c) Nursing personnel with experience in trauma care who continually monitor the trauma patient from hospital arrival to disposition to an intensive care unit, operating room, or patient care unit;

(d) Equipment for patients of all ages to include:

(i) Airway control and ventilation equipment (laryngoscopes, endotracheal tubes, bag-mask resuscitators, pocket masks, and oxygen);
(ii) Pulse oximetry;
(iii) End-tidal carbon dioxide determination equipment;
(iv) Suction devices;
(v) Electrocardiograph-oscilloscope-defibrillator with internal paddles;
(vi) Apparatus to establish central venous pressure monitoring;
(vii) Intravenous fluids and administration devices to include large bore catheters and intraosseous infusion devices;
(viii) Sterile surgical sets for airway control/cricothyrotomy, thoracotomy, vascular access, thoracostomy, peritoneal lavage, and central line insertion;
(ix) Apparatus for gastric decompression;
(x) 24-hour-per-day x-ray capability;
(xi) Two-way communication equipment for communication with the emergency transport system;
(xii) Skeletal traction devices, including capability for cervical traction;
(xiii) Arterial catheters;
(xiv) Thermal control equipment for patients;
(xv) Thermal control equipment for blood and fluids;
(xvi) Rapid infuser system;
(xvii) Broselow tape;
(xviii) Sonography; and
(xix) Doppler.

(17) An operating suite that is immediately available 24 hours per day and has:
(a) 24-hour-per-day immediate availability of in-house staffing;
(b) Equipment for patients of all ages to include:
(i) Cardiopulmonary bypass capability;
(ii) Operating microscope;
(iii) Thermal control equipment for patients
(iv) Thermal control equipment for blood and fluids;
(v) 24-hour-per-day x-ray capability including c-arm image intensifier;
(vi) Endoscopes and bronchoscopes;
(vii) Craniotomy instruments;
(viii) Capability of fixation of long-bone and pelvic fractures; and
(ix) Rapid infuser system.

(18) A postanesthetic recovery room or surgical intensive care unit that has:
(a) 24-hour-per-day in-house staffing by registered nurses;
(b) Equipment for patients of all ages to include:
(i) Capability for resuscitation and continuous monitoring of temperature, hemodynamics, and gas exchange;
(ii) Capability for continuous monitoring of intracranial pressure;
(iii) Pulse oximetry;
(iv) End-tidal carbon dioxide determination capability;
(v) Thermal control equipment for patients; and
(vi) Thermal control equipment for blood and fluids.

(19) An intensive care unit for trauma patients that has:
(a) A designated surgical director for trauma patients;
(b) A physician on duty in the intensive care unit 24 hours per day or immediately available from within the hospital as long as this physician is not the sole physician on-call for the Emergency Department;
(c) Ratio of one nurse per two patients on each shift;
(d) Equipment for patients of all ages to include:
(i) Airway control and ventilation equipment (laryngoscopes, endotracheal tubes, bag-mask resuscitators, and pocket masks);
(ii) Oxygen source with concentration controls;

(iii) Cardiac emergency cart;
(iv) Temporary, transvenous pacemaker;
(v) Electrocardiograph-oscilloscope-defibrillator with internal paddles;
(vi) Cardiac output monitoring capability;
(vii) Electronic pressure monitoring capability;
(viii) Mechanical ventilator;
(ix) Patient weighing devices;
(x) Pulmonary function measuring devices;
(xi) Temperature control devices; and
(xii) Intracranial pressure monitoring devices.

(e) Within 30 minutes of request, the ability to perform blood gas measurements, hematocrit level, and chest x-ray studies;

(20) Acute hemodialysis capability;

(21) Physician-directed burn center staffed by nursing personnel trained in burn care or a written transfer agreement with a burn center;

(22) Acute spinal cord management capability or written transfer agreement with a hospital capable of caring for a spinal cord injured patient;

(23) Radiological capabilities that include:
(a) 24-hour-per-day in-house radiology technologist;
(b) 24-hour-per-day in-house computerized tomography technologist;
(c) Sonography;
(d) Computed tomography;
(e) Angiography;
(f) Magnetic resonance imaging; and
(g) Resuscitation equipment to include: airway management and IV therapy.

(24) Respiratory therapy services available in-house 24 hours per day;

(25) 24-hour-per-day clinical laboratory service that must include:
(a) Standard analysis of blood, urine, and other body fluids, including micro-sampling when appropriate;
(b) Blood-typing and cross-matching;
(c) Coagulation studies;
(d) Comprehensive blood bank or access to community central blood bank with storage facilities;
(e) Blood gases and pH determination; and
(f) Microbiology.

(26) A rehabilitation service that provides:
(a) A staff trained in rehabilitation care of critically injured patients;
(b) For major trauma patients, functional assessment and recommendations regarding short- and long-term rehabilitation needs within one week of the patient's admission to the hospital or as soon as hemodynamically stable;
(c) Full in-house rehabilitation service or a written transfer agreement with a rehabilitation facility accredited by the Commission on Accreditation of Rehabilitation Facilities;
(d) Physical, occupational, speech therapies, and social services; and
(e) Substance abuse evaluation and counseling capability.

(27) A performance improvement program, as outlined in the North Carolina Chapter of the American College of Surgeons Committee on Trauma document "Performance Improvement Guidelines for North Carolina Trauma Centers," incorporated by reference in accordance with G.S. 150B-21.6, including subsequent amendments and editions. This document is available from the OEMS, 2707 Mail Service Center, Raleigh, North Carolina 27699-2707, at no cost. This performance improvement program must include:
(a) The trauma registry agreed to by the North Carolina State Trauma Advisory Committee and OEMS, whose data is submitted to the OEMS at least quarterly and includes all the center's trauma patients as defined in Rule .0801(33) who are either diverted to an affiliated hospital, admitted to the trauma center for greater than 23:59 hours (24 hours or more) from an ED or

hospital, die in the ED, are DOA or are transferred from the ED to the OR, ICU, or another hospital (including transfer to any affiliated hospital);

(b) Morbidity and mortality reviews to include all trauma deaths;

(c) Trauma performance committee that meets at least quarterly, to include physicians, nurses, pre-hospital personnel, and a variety of other healthcare providers, and reviews policies, procedures, and system issues and whose members or designee attends at least 50% of the regular meetings;

(d) Multidisciplinary peer review committee that meets at least quarterly and includes physicians from trauma, neurosurgery, orthopaedics, emergency medicine, anesthesiology, and other specialty physicians, as needed, specific to the case, and the trauma nurse coordinator/program manager and whose members or designee attends at least 50% of the regular meetings;

(e) Identification of discretionary and non-discretionary audit filters;

(f) Documentation and review of times and reasons for trauma-related diversion of patients from the scene or referring hospital;

(g) Documentation and review of response times for trauma surgeons, neurosurgeons, anesthesiologists or airway managers, and orthopaedists. All must demonstrate 80% compliance.

(h) Monitoring of trauma team notification times;

(i) Review of pre-hospital trauma care to include dead-on-arrivals; and

(j) Review of times and reasons for transfer of injured patients.

(28) An outreach program to include:

(a) Written transfer agreements to address the transfer and receipt of trauma patients;

(b) Programs for physicians within the community and within the referral area (to include telephone and on-site consultations) about how to access the trauma center resources and refer patients within the system;

(c) Development of a Regional Advisory Committee (RAC) as specified in Rule .1102 of this Subchapter;

(d) Development of regional criteria for coordination of trauma care;

(e) Assessment of trauma system operations at the regional level; and

(f) ATLS.

(29) A program of injury prevention and public education to include:

(a) Epidemiology research to include studies in injury control, collaboration with other institutions on research, monitoring progress of prevention programs, and consultation with qualified researchers on evaluation measures;

(b) Surveillance methods to include trauma registry data, special Emergency Department and field collection projects;

(c) Designation of a injury prevention coordinator; and

(d) Outreach activities, program development, information resources, and collaboration with existing national, regional, and state trauma programs.

(30) A trauma research program designed to produce new knowledge applicable to the care of injured patients to include:

(a) Identifiable institutional review board process;

(b) Extramural educational presentations that must include 12 education/outreach presentations over a three-year period; and

(c) 10 peer-reviewed publications over a three-year period that could come from any aspect of the trauma program.

(31) A documented continuing education program for staff physicians, nurses, allied health personnel, and community physicians to include:

(a) A general surgery residency program;

(b) 20 hours of Category I or II trauma-related continuing medical education (as approved by the Accreditation Council for Continuing Medical Education) every two years for all attending general surgeons on the trauma service, orthopaedists, and neurosurgeons, with at least 50% of this being extramural;

(c) 20 hours of Category I or II trauma-related continuing medical education (as approved by the Accreditation Council for Continuing Medical Education) every two years for all emergency physicians, with at least 50% of this being extramural;

(d) Advanced Trauma Life Support (ATLS) completion for general surgeons on the trauma service and emergency physicians. Emergency physicians, if not boarded in emergency medicine, must be current in ATLS;

(e) 20 contact hours of trauma-related continuing education (beyond in-house in-services) every two years for the trauma nurse coordinator/program manager;

(f) 16 hours of trauma-registry-related or trauma-related continuing education every two years, as deemed appropriate by the trauma nurse coordinator/program manager for the trauma registrar;

(g) At least an 80% compliance rate for 16 hours of trauma-related continuing education (as approved by the trauma nurse coordinator/program manager) every two years related to trauma care for RN's and LPN's in transport programs, Emergency Departments, primary intensive care units, primary trauma floors, and other areas deemed appropriate by the trauma nurse coordinator/program manager; and

(h) 16 hours of trauma-related continuing education every two years for mid-level practitioners routinely caring for trauma patients.

History Note: *Authority G.S. 131E-162;*
Temporary Adoption Eff. January 1, 2002;
Eff. April 1, 2003;
Amended Eff. January 1, 2004.

10A NCAC 13P .0902 LEVEL II TRAUMA CENTER CRITERIA

To receive designation as a Level II Trauma Center, a hospital shall have the following:

(1) A trauma program and a trauma service that have been operational for at least six months prior to application for designation;

(2) Membership in and inclusion of all trauma patient records in the North Carolina Trauma Registry for at least six months prior to submitting a Request for Proposal;

(3) A trauma medical director who is a board-certified general surgeon. The trauma medical director must:

(a) Have at least three years clinical experience on a trauma service or trauma fellowship training;

(b) Serve on the center's trauma service;

(c) Participate in providing care to patients with life-threatening urgent injuries;

(d) Participate in the North Carolina Chapter of the ACS' Committee on Trauma as well as other regional and national trauma organizations; and

(e) Remain a current provider in the ACS' Advanced Trauma Life Support Course and in the provision of trauma-related instruction to other health care personnel.

(4) A full-time trauma nurse coordinator (TNC)/program manager (TPM) who is a registered nurse, licensed by the North Carolina Board of Nursing;

(5) A full-time trauma registrar (TR) who has a working knowledge of medical terminology, is able to operate a personal computer, and has demonstrated the ability to extract data from the medical record;

(6) A hospital department/division/section for general surgery, neurological surgery, emergency medicine, anesthesiology, and orthopaedic surgery, with designated chair or physician liaison to the trauma program for each;

(7) Clinical capabilities in general surgery with two separate posted call schedules. One shall be for trauma, one for general surgery. In those instances where a physician may simultaneously be listed on both schedules, there must be a defined back-up surgeon listed on the schedule to allow the trauma surgeon to provide care for the trauma patient. The trauma service director shall specify, in writing, the specific credentials that each back-up surgeon must have. These must state that the back-up surgeon has surgical privileges at the trauma center and is boarded or eligible in general surgery (with board certification in general surgery within five years of completing residency). If a trauma surgeon is simultaneously on call at more than one hospital, there shall be a defined, posted trauma surgery back-up call schedule composed of surgeons credentialed to serve on the trauma panel.

(8) Response of a trauma team to provide evaluation and treatment of a trauma patient 24 hours per day that includes:
   (a) A trauma attending whose presence at the patient's bedside within 20 minutes of notification is documented and who participates in therapeutic decisions and is present at all operative procedures;
   (b) An emergency physician who is present in the Emergency Department 24 hours per day who is either board-certified or prepared in emergency medicine (by the American Board of Emergency Medicine or the American Osteopathic Board of Emergency Medicine) or board-certified or eligible by the American Board of Surgery, American Board of Family Practice, or American Board of Internal Medicine and practices emergency medicine as his primary specialty. This emergency physician if prepared or eligible must be board-certified within five years after successful completion of the residency and serves as a designated member of the trauma team until the arrival of the trauma surgeon;
   (c) Neurosurgery specialists who are never simultaneously on-call at another Level II or higher trauma center, who are promptly available, if requested by the trauma team leader, as long as there is either an in-house attending neurosurgeon; a Post Graduate Year 2 (PGY2) or higher in-house neurosurgery resident; or in-house emergency physician or the on-call trauma surgeon as long as the institution can document management guidelines and annual continuing medical education for neurosurgical emergencies. There must be a specified written back-up on the call schedule whenever the neurosurgeon is simultaneously on-call at a hospital other than the trauma center; and
   (d) Orthopaedic surgery specialists who are never simultaneously on-call at another Level II or higher trauma center, who are promptly available, if requested by the trauma team leader, as long as there is either an in-house attending orthopaedic surgeon; a Post Graduate Year 2 (PGY2) or higher in-house orthopaedic surgery resident; or in-house emergency physician or the on-call trauma surgeon as long as the institution can document management guidelines and annual continuing medical education for orthopaedic emergencies. There must be a specified written back-up on the call schedule whenever the orthopaedic surgeon is simultaneously on-call at a hospital other than the trauma center; and
   (e) An in-house anesthesiologist or a Clinical Anesthesiology Year 3 (CA3) resident unless an anesthesiologist on-call is advised and promptly available after notification or an in-house CRNA under physician supervision, practicing in accordance with G.S. 90-171.20(7)e, pending the arrival of the anesthesiologist.
(9) A written credentialing process established by the Department of Surgery to approve mid-level practitioners and attending general surgeons covering the trauma service. The surgeons must have board certification in general surgery within five years of completing residency;
(10) Neurosurgeons and orthopaedists serving the trauma service who are currently board certified or eligible. Those who are eligible must be board certified within five years after successful completion of the residency;
(11) Standard written protocols relating to trauma care management formulated and routinely updated;
(12) Criteria to ensure team activation prior to arrival of trauma/burn patients to include the following:
   (a) Shock;
   (b) Respiratory distress;
   (c) Airway compromise;
   (d) Unresponsiveness (Glasgow Coma Scale less than eight with potential for multiple injuries; and
   (e) Gunshot wound to head, neck, or torso.
(13) Surgical evaluation, based upon the following criteria, by the health professional who is promptly available:
   (a) Proximal amputations;
   (b) Burns meeting institutional transfer criteria;
   (c) Vascular compromise;
   (d) Crush to chest or pelvis;
   (e) Two or more proximal long bone fractures; and
   (f) Spinal cord injury.

(14) Surgical consults, based upon the following criteria, by the health professional who is promptly available:
- (a) Falls greater than 20 feet;
- (b) Pedestrian struck by motor vehicle;
- (c) Motor vehicle crash with:
  - (i) Ejection (includes motorcycle);
  - (ii) Rollover;
  - (iii) Speed greater than 40 mph; or
  - (iv) Death of another individual at the scene;
- (d) Extremes of age, less than five or greater than 70 years;

(15) Clinical capabilities (promptly available if requested by the trauma team leader, with a posted on-call schedule), to include individuals credentialed in the following:
- (a) Critical care;
- (b) Hand surgery;
- (c) Neurosurgery (The neurosurgeon must be dedicated to one hospital or a back-up call schedule must be available. If fewer than 25 emergency neurosurgical trauma operations are done in a year, and the neurosurgeon is dedicated only to that hospital, then a published back-up call list is not necessary.);
- (d) Obstetrics/gynecologic surgery;
- (e) Opthalmic surgery;
- (f) Oral maxillofacial surgery;
- (g) Orthopaedics (dedicated to one hospital or a back-up call schedule must be available);
- (h) Plastic surgery;
- (i) Radiology;
- (j) Thoracic surgery; and
- (k) Urologic surgery.

(16) An Emergency Department that has:
- (a) A designated physician director who is board-certified or prepared in emergency medicine (by the American Board of Emergency Medicine or the American Osteopathic Board of Emergency Medicine);
- (b) 24-hour-per-day staffing by physicians physically present in the Emergency Department who:
  - (i) Are either board-certified or prepared in emergency medicine (by the American Board of Emergency Medicine or the American Osteopathic Board of Emergency Medicine or board-certified or eligible by the American Board of Surgery, American Board of Family Practice, or American Board of Internal Medicine). These emergency physicians must be board-certified within five years after successful completion of a residency;
  - (ii) Are designated members of the trauma team; and
  - (iii) Practice emergency medicine as their primary specialty.
- (c) Nursing personnel with experience in trauma care who continually monitor the trauma patient from hospital arrival to disposition to an intensive care unit, operating room, or patient care unit;
- (d) Equipment for patients of all ages to include:
  - (i) Airway control and ventilation equipment (laryngoscopes, endotracheal tubes, bag-mask resuscitators, pocket masks, and oxygen);
  - (ii) Pulse oximetry;
  - (iii) End-tidal carbon dioxide determination equipment;
  - (iv) Suction devices;
  - (v) Electrocardiograph-oscilloscope-defibrillator with internal paddles;
  - (vi) Apparatus to establish central venous pressure monitoring;
  - (vii) Intravenous fluids and administration devices to include large bore catheters and intraosseous infusion devices;
  - (viii) Sterile surgical sets for airway control/cricothyrotomy, thoracotomy, vascular access, thoracostomy, peritoneal lavage, and central line insertion;

(ix) Apparatus for gastric decompression;
(x) 24-hour-per-day x-ray capability;
(xi) Two-way communication equipment for communication with the emergency transport system;
(xii) Skeletal traction devices, including capability for cervical traction;
(xiii) Arterial catheters;
(xiv) Thermal control equipment for patients;
(xv) Thermal control equipment for blood and fluids;
(xvi) Rapid infuser system;
(xvii) Broselow tape;
(xviii) Sonography; and
(xix) Doppler.

(17) An operating suite that is immediately available 24 hours per day and has:
(a) 24-hour-per-day immediate availability of in-house staffing;
(b) Equipment for patients of all ages to include:
(i) Thermal control equipment for patients;
(ii) Thermal control equipment for blood and fluids;
(iii) 24-hour-per-day x-ray capability, including c-arm image intensifier;
(iv) Endoscopes and bronchoscopes;
(v) Craniotomy instruments;
(vi) Capability of fixation of long-bone and pelvic fractures; and
(vii) Rapid infuser system.

(18) A postanesthetic recovery room or surgical intensive care unit that has:
(a) 24-hour-per-day in-house staffing by registered nurses;
(b) Equipment for patients of all ages to include:
(i) Capability for resuscitation and continuous monitoring of temperature, hemodynamics, and gas exchange;
(ii) Capability for continuous monitoring of intracranial pressure;
(iii) Pulse oximetry;
(iv) End-tidal carbon dioxide determination capability;
(v) Thermal control equipment for patients; and
(vi) Thermal control equipment for blood and fluids.

(19) An intensive care unit for trauma patients that has:
(a) A designated surgical director of trauma patients;
(b) A physician on duty in the intensive care unit 24 hours per day or immediately available from within the hospital as long as this physician is not the sole physician on-call for the Emergency Department;
(c) Ratio of one nurse per two patients on each shift;
(d) Equipment for patients of all ages to include:
(i) Airway control and ventilation equipment (laryngoscopes, endotracheal tubes, bag-mask resuscitators, and pocket masks);
(ii) Oxygen source with concentration controls;
(iii) Cardiac emergency cart;
(iv) Temporary transvenous pacemaker;
(v) Electrocardiograph-oscilloscope-defibrillator with internal paddles;
(vi) Cardiac output monitoring capability;
(vii) Electronic pressure monitoring capability;
(viii) Mechanical ventilator;
(ix) Patient weighing devices;
(x) Pulmonary function measuring devices;
(xi) Temperature control devices; and
(xii) Intracranial pressure monitoring devices.
(e) Within 30 minutes of request, the ability to perform blood gas measurements, hematocrit level, and chest x-ray studies.

(20) Acute hemodialysis capability or utilization of a written transfer agreement;

(21) Physician-directed burn center staffed by nursing personnel trained in burn care or a written transfer agreement with a burn center;

(22) Acute spinal cord management capability or written transfer agreement with a hospital capable of caring for a spinal cord injured patient;

(23) Radiological capabilities that include:

(a) 24-hour-per-day in-house radiology technologist;

(b) 24-hour-per-day in-house computerized tomography technologist;

(c) Sonography;

(d) Computed tomography;

(e) Angiography; and

(f) Resuscitation equipment to include airway management and IV therapy.

(24) Respiratory therapy services available in-house 24 hours per day;

(25) 24-hour-per-day clinical laboratory service that must include:

(a) Standard analysis of blood, urine, and other body fluids, including micro-sampling when appropriate;

(b) Blood-typing and cross-matching;

(c) Coagulation studies;

(d) Comprehensive blood bank or access to a community central blood bank with storage facilities;

(e) Blood gases and pH determination; and

(f) Microbiology.

(26) A rehabilitation service that provides:

(a) A staff trained in rehabilitation care of critically injured patients;

(b) For major trauma patients, functional assessment and recommendation regarding short- and long-term rehabilitation needs within one week of the patient's admission to the hospital or as soon as hemodynamically stable;

(c) Full in-house rehabilitation service or a written transfer agreement with a rehabilitation facility accredited by the Commission on Accreditation of Rehabilitation Facilities;

(d) Physical, occupational, speech therapies, and social services; and

(e) Substance abuse evaluation and counseling capability.

(27) A performance improvement program, as outlined in the North Carolina Chapter of the American College of Surgeons Committee on Trauma document "Performance Improvement Guidelines for North Carolina Trauma Centers," incorporated by reference in accordance with G.S. 150B-21.6, including subsequent amendments and editions. This document is available from the OEMS, 2707 Mail Service Center, Raleigh, North Carolina 27699-2707, at no cost. This performance improvement program must include:

(a) The trauma registry agreed to by the North Carolina State Trauma Advisory Committee and OEMS whose data is submitted to the OEMS at least quarterly and includes all the center's trauma patients as defined in Rule .0801(33) who are either diverted to an affiliated hospital, admitted to the trauma center for greater than 23:59 hours (24 hours or more) from an ED or hospital, die in the ED, are DOA or are transferred from the ED to the OR, ICU, or another hospital (including transfer to any affiliated hospital);

(b) Morbidity and mortality reviews to include all trauma deaths;

(c) Trauma performance committee that meets at least quarterly, to include physicians, nurses, pre-hospital personnel, and a variety of other healthcare providers, and reviews policies, procedures, and system issues and whose members or designee attends at least 50% of the regular meetings;

(d) Multidisciplinary peer review committee that meets at least quarterly and includes physicians from trauma, neurosurgery, orthopaedics, emergency medicine, anesthesiology, and other specialty physicians, as needed, specific to the case, and the trauma nurse coordinator/program manager and whose members or designee attends at least 50% of the regular meetings;

(e) Identification of discretionary and non-discretionary audit filters;

(f) Documentation and review of times and reasons for trauma-related diversion of patients from the scene or referring hospital;

(g) Documentation and review of response times for trauma surgeons, neurosurgeons, anesthesiologists or airway managers, and orthopaedists. All must demonstrate 80% compliance;
(h) Monitoring of trauma team notification times;
(i) Review of pre-hospital trauma care to include dead-on-arrivals; and
(j) Review of times and reasons for transfer of injured patients.

(28) An outreach program to include:
(a) Written transfer agreements to address the transfer and receipt of trauma patients;
(b) Programs for physicians within the community and within the referral area (to include telephone and on-site consultations) about how to access the trauma center resources and refer patients within the system;
(c) Development of a Regional Advisory Committee (RAC) as specified in Rule .1102 of this Subchapter;
(d) Development of regional criteria for coordination of trauma care; and
(e) Assessment of trauma system operations at the regional level.

(29) A program of injury prevention and public education to include:
(a) Designation of an injury prevention coordinator; and
(b) Outreach activities, program development, information resources, and collaboration with existing national, regional, and state trauma programs.

(30) A documented continuing education program for staff physicians, nurses, allied health personnel, and community physicians to include:
(a) 20 hours of Category I or II trauma-related continuing medical education (as approved by the Accreditation Council for Continuing Medical Education) every two years for all attending general surgeons on the trauma service, orthopaedics, and neurosurgeons, with at least 50% of this being extramural;
(b) 20 hours of Category I or II trauma-related continuing medical education (as approved by the Accreditation Council for Continuing Medical Education) every two years for all emergency physicians, with at least 50% of this being extramural;
(c) Advanced Trauma Life Support (ATLS) completion for general surgeons on the trauma service and emergency physicians. Emergency physicians, if not boarded in emergency medicine, must be current in ATLS.
(d) 20 contact hours of trauma-related continuing education (beyond in-house in-services) every two years for the trauma nurse coordinator/program manager;
(e) 16 hours of trauma-registry-related or trauma-related continuing education every two years, as deemed appropriate by the trauma nurse coordinator/program manager, for the trauma registrar;
(f) at least 80% compliance rate for 16 hours of trauma-related continuing education (as approved by the trauma nurse coordinator/program manager) every two years related to trauma care for RN's and LPN's in transport programs, Emergency Departments, primary intensive care units, primary trauma floors, and other areas deemed appropriate by the trauma nurse coordinator/program manager; and
(g) 16 contact hours of trauma-related continuing education every two years for mid-level practitioners routinely caring for trauma patients.

History Note: *Authority G.S. 131E-162;*
Temporary Adoption Eff. January 1, 2002;
Eff. April 1, 2003;
Amended Eff. January 1, 2004.

10A NCAC 13P .0903 LEVEL III TRAUMA CENTER CRITERIA

To receive designation as a Level III Trauma Center, a hospital shall have the following:

(1) A trauma program and a trauma service that have been operational for at least six months prior to application for designation;
(2) Membership in and inclusion of all trauma patient records in the North Carolina Trauma Registry for at least six months prior to submitting a Request for Proposal application;

(3) A trauma medical director who is a board-certified general surgeon. The trauma medical director must:
   (a) Serve on the center's trauma service;
   (b) Participate in providing care to patients with life-threatening or urgent injuries;
   (c) Participate in the North Carolina Chapter of the ACS' Committee on Trauma;
   (d) Remain a current provider in the ACS' Advanced Trauma Life Support Course in the provision of trauma-related instruction to other health care personnel.

(4) A designated trauma nurse coordinator (TNC)/program manager (TPM) who is a registered nurse, licensed by the North Carolina Board of Nursing;

(5) A trauma registrar (TR) who has a working knowledge of medical terminology, is able to operate a personal computer, and has demonstrated the ability to extract data from the medical record;

(6) A hospital department/division/section for general surgery, emergency medicine, anesthesiology, and orthopaedic surgery, with designated chair or physician liaison to the trauma program for each;

(7) Clinical capabilities in general surgery with a written posted call schedule that indicates who is on call for both trauma and general surgery. If a trauma surgeon is simultaneously on call at more than one hospital, there must be a defined, posted trauma surgery back-up call schedule composed of surgeons credentialed to serve on the trauma panel. The trauma service director shall specify, in writing, the specific credentials that each back-up surgeon must have. These must state that the back-up surgeon has surgical privileges at the trauma center and is boarded or eligible in general surgery (with board certification in general surgery within five years of completing residency).

(8) Response of a trauma team to provide evaluation and treatment of a trauma patient 24 hours per day that includes:
   (a) A trauma attending whose presence at the patient's bedside within 30 minutes of notification is documented and who participates in therapeutic decisions and is present at all operative procedures;
   (b) An emergency physician who is present in the Emergency Department 24 hours per day who is either board-certified or prepared in emergency medicine (by the American Board of Emergency Medicine or the American Osteopathic Board of Emergency Medicine) or board-certified or eligible by the American Board of Surgery, American Board of Family Practice, or American Board of Internal Medicine and practices emergency medicine as his primary specialty. This emergency physician if prepared or eligible must be board-certified within five years after successful completion of the residency and serve as a designated member of the trauma team until the arrival of the trauma surgeon;
   (c) An anesthesiologist who is on-call and promptly available after notification by the trauma team leader or an in-house CRNA under physician supervision, practicing in accordance with G.S. 90-171.20(7)e, pending the arrival of the anesthesiologist within 20 minutes of notification.

(9) A written credentialing process established by the Department of Surgery to approve mid-level practitioners and attending general surgeons covering the trauma service. The surgeons must have board certification in general surgery within five years of completing residency;

(10) Current board certification or eligibility of orthopaedists, with board certification within five years after successful completion of residency;

(11) Standard written protocols relating to trauma care management formulated and routinely updated;

(12) Criteria to ensure team activation prior to arrival of trauma/burn patients to include the following:
   (a) Shock;
   (b) Respiratory distress;
   (c) Airway compromise;
   (d) Unresponsiveness (Glasgow Coma Scale less than eight) with potential for multiple injuries; and
   (e) Gunshot wound to head, neck, or torso.

(13) Surgical evaluation, based upon the following criteria, by the health professional who is promptly available:
   (a) Proximal amputations;
   (b) Burns meeting institutional transfer criteria;
   (c) Vascular compromise;
   (d) Crush to chest or pelvis;

(e) Two or more proximal long bone fractures; and
(f) Spinal cord injury.

(14) Surgical consults, based upon the following criteria, by the health professional who is promptly available:
(a) Falls greater than 20 feet;
(b) Pedestrian struck by motor vehicle;
(c) Motor vehicle crash with:
(i) Ejection (includes motorcycle);
(ii) Rollover;
(iii) Speed greater than 40 mph; or
(iv) Death of another individual at the scene;
(d) Extremes of age, less than five or greater than 70 years;

(15) Clinical capabilities (promptly available if requested by the trauma team leader, with a posted on-call schedule) to include individuals credentialed in the following:
(a) Orthopaedics; and
(b) Radiology.

(16) An Emergency Department that has:
(a) A designated physician director who is board-certified or prepared in emergency medicine (by the American Board of Emergency Medicine or the American Osteopathic Board of Emergency Medicine);
(b) 24-hour-per-day staffing by physicians physically present in the Emergency Department who:
(i) Are either board-certified or prepared in emergency medicine (by the American Board of Emergency Medicine or the American Osteopathic Board of Emergency Medicine) or board-certified or eligible by the American Board of Surgery, American Board of Family Practice, or American Board of Internal Medicine. These emergency physicians must be board-certified within five years after successful completion of a residency;
(ii) Are designated members of the trauma team; and
(iii) Practice emergency medicine as their primary specialty.
(c) Nursing personnel with experience in trauma care who continually monitor the trauma patient from hospital arrival to disposition to an intensive care unit, operating room, or patient care unit;
(d) Resuscitation equipment for patients of all ages to include:
(i) Airway control and ventilation equipment (laryngoscopes, endotracheal tubes, bag-mask resuscitators, pocket masks, and oxygen);
(ii) Pulse oximetry;
(iii) End-tidal carbon dioxide determination equipment;
(iv) Suction devices;
(v) Electrocardiograph-oscilloscope-defibrillator with internal paddles;
(vi) Apparatus to establish central venous pressure monitoring;
(vii) Intravenous fluids and administration devices to include large bore catheters and intraosseous infusion devices;
(viii) Sterile surgical sets for airway control/cricothyrotomy, thoracotomy, vascular access, thoracostomy, peritoneal lavage, and central line insertion;
(ix) Apparatus for gastric decompression;
(x) 24-hour-per-day x-ray capability;
(xi) Two-way communication equipment for communication with the emergency transport system;
(xii) Skeletal traction devices;
(xiii) Thermal control equipment for patients; and
(xiv) Thermal control equipment for blood and fluids;
(xv) Rapid infuser system;
(xvi) Broselow tape; and
(xvii) Doppler.

(17) An operating suite that has:
- (a) Personnel available 24 hours a day, on-call, and available within 30 minutes of notification unless in-house;
- (b) Age-specific equipment to include:
  - (i) Thermal control equipment for patients;
  - (ii) Thermal control equipment for blood and fluids;
  - (iii) 24-hour-per-day x-ray capability, including c-arm image intensifier;
  - (iv) Endoscopes and bronchoscopes;
  - (v) Equipment for long bone and pelvic fracture fixation; and
  - (vi) Rapid infuser system.

(18) A postanesthetic recovery room or surgical intensive care unit that has:
- (a) 24-hour-per-day availability of registered nurses within 30 minutes from inside or outside the hospital;
- (b) Equipment for patients of all ages to include:
  - (i) Capability for resuscitation and continuous monitoring of temperature, hemodynamics, and gas exchange;
  - (ii) Pulse oximetry;
  - (iii) End-tidal carbon dioxide determination;
  - (iv) Thermal control equipment for patients; and
  - (v) Thermal control equipment for blood and fluids.

(19) An intensive care unit for trauma patients that has:
- (a) A designated surgical director of trauma patients;
- (b) A physician on duty in the intensive care unit 24-hours-per-day or immediately available from within the hospital (which may be a physician who is the sole physician on-call for the Emergency Department);
- (c) Equipment for patients of all ages to include:
  - (i) Airway control and ventilation equipment (laryngoscopes, endotracheal tubes, bag-mask resuscitators and pocket masks);
  - (ii) Oxygen source with concentration controls;
  - (iii) Cardiac emergency cart;
  - (iv) Temporary transvenous pacemaker;
  - (v) Electrocardiograph-oscilloscope-defibrillator;
  - (vi) Cardiac output monitoring capability;
  - (vii) Electronic pressure monitoring capability;
  - (viii) Mechanical ventilator;
  - (ix) Patient weighing devices;
  - (x) Pulmonary function measuring devices; and
  - (xi) Temperature control devices.
- (d) Within 30 minutes of request, the ability to perform blood gas measurements, hematocrit level, and chest x-ray studies;

(20) Acute hemodialysis capability or utilization of a written transfer agreement;

(21) Physician-directed burn center staffed by nursing personnel trained in burn care or a written transfer agreement with a burn center;

(22) Acute spinal cord management capability or written transfer agreement with a hospital capable of caring for a spinal cord injured patient;

(23) Acute head injury management capability or written transfer agreement with a hospital capable of caring for a head injury;

(24) Radiological capabilities that include:
- (a) Radiology technologist and computer tomography technologist available within 30 minutes of notification or documentation that procedures are available within 30 minutes;
- (b) Computed Tomography;
- (c) Sonography; and
- (d) Resuscitation equipment to include airway management and IV therapy.

(25) Respiratory therapy services on-call 24 hours per day;

(26) 24-hour-per-day clinical laboratory service that must include:

(a) Standard analysis of blood, urine, and other body fluids, including micro-sampling when appropriate;
(b) Blood-typing and cross-matching;
(c) Coagulation studies;
(d) Comprehensive blood bank or access to a community central blood bank with storage facilities;
(e) Blood gases and pH determination; and
(f) Microbiology.

(27) Full in-house rehabilitation service or written transfer agreement with a rehabilitation facility accredited by the Commission on Accreditation of Rehabilitation Facilities;

(28) Physical therapy and social services.

(29) A performance improvement program, as outlined in the North Carolina Chapter of the American College of Surgeons Committee on Trauma document "Performance Improvement Guidelines for North Carolina Trauma Centers," incorporated by reference in accordance with G.S. 150B-21.6, including subsequent amendments and editions. This document is available from the OEMS, 2707 Mail Service Center, Raleigh, North Carolina 27699-2707, at no cost. This performance improvement program must include:
(a) The trauma registry agreed to by the North Carolina State Trauma Advisory Committee and OEMS, whose data is submitted to the OEMS at least quarterly and includes all the center's trauma patients as defined in Rule .0801(33) who are either diverted to an affiliated hospital, admitted to the trauma center for greater than 23:59 hours (24 hours or more) from an ED or hospital, die in the ED, are DOA or are transferred from the ED to the OR, ICU, or another hospital (including transfer to any affiliated hospital);
(b) Morbidity and mortality reviews to include all trauma deaths;
(c) Trauma performance committee that meets at least quarterly, to include physicians, nurses, pre-hospital personnel, and a variety of other healthcare providers, and reviews policies, procedures, and system issues and whose members or designee attends at least 50% of the regular meetings;
(d) Multidisciplinary peer review committee that meets at least quarterly and includes physicians from trauma, emergency medicine, and other specialty physicians as needed specific to the case, and the trauma nurse coordinator/program manager and whose members or designee attends at least 50% of the regular meetings;
(e) Identification of discretionary and non-discretionary audit filters;
(f) Documentation and review of times and reasons for trauma-related diversion of patients from the scene or referring hospital;
(g) Documentation and review of response times for trauma surgeons, airway managers, and orthopaedists. All must demonstrate 80% compliance;
(h) Monitoring of trauma team notification times;
(i) Documentation (unless in-house) and review of Emergency Department response times for anesthesiologists or airway managers and computerized tomography technologist;
(j) Documentation of availability of the surgeon on-call for trauma, such that compliance is 90% or greater where there is no trauma surgeon back-up call schedule;
(k) Trauma performance and multidisciplinary peer review committees may be incorporated together or included in other staff meetings as appropriate for the facility performance improvement rules;
(l) Review of pre-hospital trauma care to include dead-on-arrivals; and
(m) Review of times and reasons for transfer of injured patients.

(30) An outreach program to include:
(a) Written transfer agreements to address the transfer and receipt of trauma patients;
(b) Participation in a Regional Advisory Committee (RAC).

(31) Coordination or participation in community prevention activities;

(32) A documented continuing education program for staff physicians, nurses, allied health personnel, and community physicians to include:

(a) 20 hours of Category I or II trauma-related continuing medical education (as approved by the Accreditation Council for Continuing Medical Education every two years for all attending general surgeons on the trauma service, with at least 50% of this being extramural;

(b) 20 hours of Category I or II trauma-related continuing medical education (as approved by the Accreditation Council for Continuing Medical Education every two years for all emergency physicians, with at least 50% of this being extramural;

(c) Advanced Trauma Life Support (ATLS) completion for general surgeons on the trauma service and emergency physicians. Emergency physicians, if not boarded in emergency medicine, must be current in ATLS;

(d) 20 contact hours of trauma-related continuing education (beyond in-house in- services) every two years for the trauma nurse coordinator/program manager;

(e) 16 hours of trauma-registry-related or trauma-related continuing education every two years, as deemed appropriate by the trauma nurse coordinator/program manager, for the trauma registrar;

(f) At least an 80% compliance rate for 16 hours of trauma-related continuing education (as approved by the trauma nurse coordinator/program manager) every two years related to trauma care for RN's and LPN's in transport programs, Emergency Departments, primary intensive care units, primary trauma floors, and other areas deemed appropriate by the trauma nurse coordinator/program manager; and

(g) 16 hours of trauma-related continuing education every two years for mid-level practitioners routinely caring for trauma patients.

History Note: *Authority G.S. 131E-162;*
Temporary Adoption Eff. January 1, 2002;
Eff. April 1, 2003;
Amended Eff. January 1, 2004.

10A NCAC 13P .0904 INITIAL DESIGNATION PROCESS

(a) For initial trauma center designation, the hospital shall request a consult visit by OEMS and have the consult within one year prior to submission of the RFP.

(b) A hospital interested in pursuing trauma center designation shall submit a letter of intent 180 days prior to the submission of an RFP to the OEMS. The letter shall also define the hospital's primary trauma catchment area. Simultaneously, Level I or II applicants shall also demonstrate the need for the trauma center designation by submitting one original and three copies of documents that include at a minimum:

(1) The population to be served and the extent to which the population is underserved for trauma care with the methodology used to reach this conclusion;

(2) Geographic considerations to include trauma primary and secondary catchment area and distance from other trauma centers; and

(3) Trauma patient volume and severity of injury for the facility for the 24-month period of time preceding the application. The trauma center shall show that its trauma service will be taking care of at least 200 trauma patients with an Injury Severity Score (ISS) greater than or equal to 15 during the first 2-year period of its designation. This criteria shall be met without compromising the quality of care or cost effectiveness of any other designated Level I or II trauma center sharing all or part of its catchment area or by jeopardizing the existing trauma center's ability to meet this same 200-patient minimum.

(c) Following receipt of the letter of intent by OEMS, any designated Level I or II trauma center(s) sharing all or part of the applicant's catchment area must provide to OEMS a trauma registry download for the same two-year period used by the applicant. This download shall be provided within 30 days of the request of OEMS.

(d) OEMS shall review the regional data, from both the applicant and the existing trauma center(s), and ascertain the applicant's ability to satisfy the justification of need information required in Paragraphs (b)(1) – (3) of this Rule. Simultaneously, the applicant's primary RAC shall be notified of the application and be provided the regional data as required in Paragraphs (b)(1) – (3) of this Rule submitted by the applicant for review and comment. The RAC shall be given a minimum of 30 days to submit any concerns in writing for OEMS' consideration. If no comments are received, OEMS shall proceed.

(e) OEMS shall notify the hospital in writing of its decision to allow submission of an RFP. The RAC shall also be notified so that any necessary changes in protocols can be considered.

(f) OEMS shall also notify the respective Board of County Commissioners in the applicant's trauma primary catchment area of the request for initial designation to allow for comment.
(g) Hospitals desiring to be considered for initial trauma center designation shall complete and submit an original and five copies of bound, page-numbered RFP to the OEMS at least 90 days prior to the proposed site visit date.
(h) For Level I, II, and III applicants, the RFP shall demonstrate that the hospital meets the standards for the designation level applied for as found in Rules .0901, .0902, or .0903 of this Section.
(i) If OEMS does not recommend a site visit, based upon failure to comply with Rules .0901, .0902, or .0903, the reasons shall be forwarded to the hospital in writing within 30 days of the decision. The hospital may reapply for designation within six months following the submission of an updated RFP. If the hospital fails to respond within six months, the hospital shall reapply following the process outlined in Paragraphs (a) – (h) of this Rule.
(j) If the OEMS recommends the hospital for a site visit, the hospital shall be notified within 30 days and the site visit shall be conducted within six months of the recommendation. The site visit shall be scheduled on a date mutually agreeable to the hospital and the OEMS.
(k) Any in-state reviewer for a Level I or II visit (except the OEMS representatives) shall be from outside the planning region in which the hospital is located. The composition of a Level I or II state site survey team shall be as follows:

(1) One out-of-state Fellow of the ACS, experienced as a site surveyor, who shall be designated the primary reviewer.
(2) One emergency physician who currently works in a designated trauma center, is a member of the North Carolina College of Emergency Physicians, and is boarded in emergency medicine (by the American Board of Emergency Medicine or the American Osteopathic Board of Emergency Medicine),
(3) One in-state trauma surgeon who is a member of the North Carolina Committee on Trauma;
(4) One out-of-state trauma nurse coordinator/program manager;
(5) The medical director of the OEMS; and
(6) The Hospitals Specialist of the OEMS.

(l) All site team members for a Level III visit shall be from in-state, and all (except for the OEMS representatives) shall be from outside the planning region in which the hospital is located. The composition of a Level III state site survey team shall be as follows:

(1) One Fellow of the ACS, who is a member of the North Carolina Committee on Trauma and shall be designated the primary reviewer;
(2) One emergency physician who currently works in a designated trauma center, is a member of the North Carolina College of Emergency Physicians, and is boarded in emergency medicine (by the American Board of Emergency Medicine or the American Osteopathic Board of Emergency Medicine).
(3) A trauma nurse coordinator/program manager;
(4) The medical director of the OEMS; and
(5) The Hospitals Specialist of the OEMS.

(m) On the day of the site visit the hospital shall make available all requested patient medical charts.
(n) A post-conference report based on the consensus of the site review team shall be given verbally during a summary conference. A written consensus report will be completed, to include a peer review report, by the primary reviewer and submitted to OEMS within 30 days of the site visit.
(o) The report of the site survey team and the staff recommendations shall be reviewed by the State Emergency Medical Services Advisory Council at its next regularly scheduled meeting which is more than 45 days following the site visit. Based upon the site visit report and the staff recommendation, the State Emergency Medical Services Advisory Council shall recommend to the OEMS that the request for trauma center designation be approved or denied.
(p) All criteria defined in Rule .0901, .0902, or .0903 of this Section shall be met for initial designation at the level requested. Initial designation shall not be granted if deficiencies exist.
(q) Hospitals with a deficiency(ies) may be given up to 12 months to demonstrate compliance. Satisfaction of deficiency(ies) may require an additional site visit. If compliance is not demonstrated within the time period, to be defined by OEMS, the hospital shall be required to submit a new application and updated RFP and follow the process outlined in Paragraphs (a) – (h) of this Rule.
(r) The final decision regarding trauma center designation shall be rendered by the OEMS.
(s) The hospital shall be notified, in writing, of the State Emergency Medical Services Advisory Council's and OEMS' final recommendation within 30 days of the Advisory Council meeting.

(t) If a trauma center changes its trauma program administrative structure (such that the trauma service, trauma medical director, trauma nurse coordinator/program manager and/or trauma registrar are relocated on the hospital's organizational chart) at any time, it shall notify OEMS of this change in writing within 30 days of the occurrence.
(u) Initial designation as a trauma center is valid for a period of three years.

History Note: *Authority G.S. 131E-162; 143-509(3);*
Temporary Adoption Eff. January 1, 2002;
Eff. April 1, 2003.

10A NCAC 13P .0905 RENEWAL DESIGNATION PROCESS

(a) One of two options may be utilized to achieve trauma center renewal:
- (1) Undergo a site visit conducted by OEMS to obtain a four-year renewal designation; or
- (2) Undergo a verification visit arranged by the ACS, in conjunction with OEMS, to obtain a three- year renewal designation;

(b) For hospitals choosing Subparagraph (a)(1) of this Rule:
- (1) Prior to the end of the designation period, the OEMS shall forward to the hospital an RFP for completion. The hospital shall, within 10 days of receipt of the RFP, define for OEMS the trauma center's trauma primary catchment area. Upon this notification, OEMS shall notify the respective Board of County Commissioners in the applicant's trauma primary catchment area of the request for renewal to allow for comment.
- (2) Hospitals seeking a renewal of trauma center designation shall complete and submit an original and five copies of a bound, page-numbered RFP as directed by the OEMS to the OEMS and the specified site surveyors at least 30 days prior to the site visit. The RFP shall include information that supports compliance with the criteria contained in Rule .0901, .0902, or .0903 of this Section as it relates to the trauma center's level of designation.
- (3) All criteria defined in Rule .0901, .0902, or .0903 of this Section, as relates to the trauma center's level of designation, shall be met for renewal designation.
- (4) A site visit shall be conducted within 120 days prior to the end of the designation period. The site visit shall be scheduled on a date mutually agreeable to the hospital and the OEMS.
- (5) The composition of a Level I or II site survey team shall be the same as that specified in Rule .0904(k) of this Section.
- (6) The composition of a Level III site survey team shall be the same as that specified in Rule .0904(l) of this Section.
- (7) On the day of the site visit the hospital shall make available all requested patient medical charts.
- (8) A post-conference report based on consensus of the site review team shall be given verbally during the summary conference. A written consensus report shall be completed, to include a peer review report, by the primary reviewer and submitted to OEMS within 30 days of the site visit.
- (9) The report of the site survey team and a staff recommendation shall be reviewed by the State Emergency Medical Services Advisory Council at its next regularly scheduled meeting which is more than 30 days following the site visit. Based upon the site visit report and the staff recommendation, the State Emergency Medical Services Advisory Council shall recommend to the OEMS that the request for trauma center renewal be approved; approved with a contingency(ies) due to a deficiency(ies) requiring a focused review; approved with a contingency(ies) not due to a deficiency(ies); or denied.
- (10) Hospitals with a deficiency(ies) have up to 10 working days prior to the State EMS Advisory Council meeting to provide documentation to demonstrate compliance. If the hospital has a deficiency that cannot be corrected in this period prior to the State EMS Advisory Council meeting, the hospital, instead of a four-year renewal, may be given a time period (up to 12 months) to demonstrate compliance and undergo a focused review, that may require an additional site visit. The hospital shall retain its trauma center designation during the focused review period. If compliance is demonstrated within the prescribed time period, the hospital shall be granted its designation for the four-year period from the previous designation's expiration date. If compliance is not demonstrated within the time period, as specified by OEMS, the trauma center designation shall not be renewed. To become redesignated, the hospital shall be required to submit an updated RFP and follow the initial applicant process outlined in Rule .0904 of this Section.
- (11) The final decision regarding trauma center renewal shall be rendered by the OEMS.

(12) The hospital shall be notified in writing of the State Emergency Medical Services Advisory Council's and OEMS' final recommendation within 30 days of the Advisory Council meeting.

(13) The four-year renewal date that may be eventually granted shall not be extended due to the focused review period.

(14) Hospitals in the process of satisfying contingencies placed on them prior to December 31, 2001, shall be evaluated based on the rules that were in effect at the time of their renewal visit.

(c) For hospitals choosing Subparagraph (a)(2) of this Rule:

(1) At least six months prior to the end of the trauma center's designation period, the trauma center must notify the OEMS of its intent to undergo an ACS verification visit. It must simultaneously define in writing to the OEMS its trauma primary catchment area. Trauma centers choosing this option must then comply with all the ACS' verification procedures, as well as any additional state criteria as outlined in Rule .0901, .0902, or .0903, as apply to their level of designation.

(2) If a trauma center currently using the ACS' verification process chooses not to renew using this process, it must notify the OEMS at least six months prior to the end of its state trauma center designation period of its intention to exercise the option in Subparagraph (a)(1) of this Rule.

(3) When completing the ACS' documentation for verification, the trauma center must simultaneously submit two identical copies to OEMS. The trauma center must simultaneously complete documents supplied by OEMS to verify compliance with additional North Carolina criteria (i.e., criteria that exceed the ACS criteria) and forward these to OEMS and the ACS.

(4) The OEMS shall notify the Board of County Commissioners within the trauma center's trauma primary catchment area of the trauma center's request for renewal to allow for comments.

(5) The trauma center must make sure the site visit is scheduled to ensure that the ACS' final written report, accompanying medical record reviews and cover letter are received by OEMS at least 30 days prior to a regularly scheduled State Emergency Medical Services Advisory Council meeting to ensure that the trauma center's state designation period does not terminate without consideration by the State Emergency Medical Services Advisory Council.

(6) The composition of the Level I or Level II site team must be as specified in Rule .0904(k) of this Section, except that both the required trauma surgeons and the emergency physician may be from out-of-state. Neither North Carolina Committee on Trauma nor North Carolina College of Emergency Physician membership shall be required of the surgeons or emergency physician, respectively, if from out-of-state.

(7) The composition of the Level III site team must be as specified in Rule .0904(l) of this Section, except that the trauma surgeon, emergency physician, and trauma nurse coordinator/program manager may be from out-of-state. Neither North Carolina Committee on Trauma nor North Carolina College of Emergency Physician membership shall be required of the surgeon or emergency physician, respectively, if from out-of-state.

(8) All state trauma center criteria must be met as defined in Rules .0901, .0902, and 0903, for renewal of state designation. An ACS' verification is not required for state designation. An ACS' verification does not ensure a state designation.

(9) The final written report issued by the ACS' verification review committee, the accompanying medical record reviews (from which all identifiers may be removed), and cover letter must be forwarded to OEMS within 10 working days of its receipt by the trauma center seeking renewal.

(10) The written reports from the ACS and the OEMS staff recommendation shall be reviewed by the State Emergency Medical Services Advisory Council at its next regularly scheduled meeting. The State EMS Advisory Council shall recommend to OEMS that the request for trauma center renewal be approved; approved with a contingency(ies) due to a deficiency(ies) requiring a focused review; approved with a contingency(ies) not due to a deficiency(ies); or denied.

(11) The hospital shall be notified in writing of the State Emergency Medical Services Advisory Council's and OEMS' final recommendation within 30 days of the Advisory Council meeting.

(12) Hospitals with contingencies, as the result of a deficiency(ies), as determined by OEMS, have up to 10 working days prior to the State EMS Advisory Council meeting to provide documentation to demonstrate compliance. If the hospital has a deficiency that cannot be corrected in this time period prior to the State EMS Advisory Council meeting, the hospital, instead of a four-year renewal, may undergo a focused review (to be conducted by the OEMS) whereby the trauma center may be given up to 12 months to demonstrate compliance. Satisfaction of contingency(ies) may require an additional

site visit. The hospital shall retain its trauma center designation during the focused review period. If compliance is demonstrated within the prescribed time period, the hospital shall be granted its designation for the four-year period from the previous designation's expiration date. If compliance is not demonstrated within the time period, as specified by OEMS, the trauma center designation shall not be renewed. To become redesignated, the hospital shall be required to submit a new RFP and follow the initial applicant process outlined in Rule .0904 of this Section.

History Note: *Authority G.S. 131E-162; 143-509(3);*
Temporary Adoption Eff. January 1, 2002;
Eff. April 1, 2003;
Amended Eff. January 1, 2004.

SECTION .1000 – TRAUMA CENTER DESIGNATION ENFORCEMENT

10A NCAC 13P .1001 DENIAL, FOCUSED REVIEW, VOLUNTARY WITHDRAWAL, OR REVOCATION OF TRAUMA CENTER DESIGNATION

(a) The OEMS may deny the initial or renewal designation (without first allowing a focused review) of a trauma center for any of the following reasons:

(1) Failure to comply with G.S. 131E-162 and the rules adopted under that article; or
(2) Attempting to obtain a trauma center designation through fraud or misrepresentation; or
(3) Endangerment to the health, safety, or welfare of patients cared for in the hospital; or
(4) Repetition of contingencies placed on the trauma center in previous site visits.

(b) When a trauma center is required to have a focused review, an option only for a trauma center seeking renewal, it must be able to demonstrate compliance with the provisions of G.S.131E-162 and the rules adopted under that article within one year or less as required and delineated in writing by OEMS.

(c) The OEMS may revoke a trauma center designation at any time or deny a request for renewal of designation, whenever the OEMS finds that the trauma center has failed to comply with the provisions of G.S. 131E-162 and the rules adopted under that article; and

(1) It is not probable that the trauma center can remedy the deficiencies within one year or less; or
(2) Although the trauma center may be able to remedy the deficiencies within a reasonable period of time, it is not probable that the trauma center shall be able to remain in compliance with designation rules for the foreseeable future; or
(3) The trauma center fails to meet the requirements of a focused review; or
(4) Failure to comply endangers the health, safety, or welfare of patients cared for in the trauma center.

(d) The OEMS shall give the trauma center written notice of revocation. This notice shall be given personally or by certified mail and shall set forth:

(1) The factual allegations;
(2) The statutes or rules alleged to be violated; and
(3) Notice of the hospital's right to a contested case hearing on the amendment of the designation.

(e) Focused review is not a procedural prerequisite to the revocation of a designation pursuant to Paragraph (d) of this Rule.

(f) With the OEMS' approval, a trauma center may voluntarily withdraw its designation for a maximum of one year by submitting a written request. This request shall include the reasons for withdrawal and a plan for resolution of the issues. To reactivate the designation, the facility shall provide written documentation of compliance that is acceptable to the OEMS. Voluntary withdrawal shall not affect the original expiration date of the trauma center's designation.

(g) If the trauma center fails to resolve the issues which resulted in a voluntary withdrawal within the specified time period for resolution, the OEMS may revoke the trauma center designation.

(h) In the event of a revocation or voluntary withdrawal, the OEMS shall provide written notification to all hospitals and emergency medical services providers within the trauma center's defined trauma primary catchment area. The OEMS shall provide written notification to same if, and when, the voluntary withdrawal reactivates to full designation.

History Note: *Authority G.S. 131E-162;*
Temporary Adoption Eff. January 1, 2002;
Eff. April 1, 2003.

10A NCAC 13P .1002 PROCEDURES FOR APPEAL OF DENIAL, FOCUSED REVIEW, OR REVOCATION

Appeal of denial or revocation of a trauma center designation shall follow the law regarding contested cases found in G.S. 150B.

History Note: *Authority G.S. 131E-162;*
Temporary Adoption Eff. January 1, 2002;
Eff. April 1, 2003.

10A NCAC 13P .1003 MISREPRESENTATION OF DESIGNATION

(a) Hospitals shall not represent themselves as trauma centers unless they are currently designated by the Department pursuant to Section .0900 of this Subchapter.
(b) Designation applies only to the hospital that submitted the RFP and underwent the formal site survey and does not extend to its satellite facilities or affiliates.

History Note: *Authority G.S. 131E-162;*
Temporary Adoption Eff. January 1, 2002;
Eff. April 1, 2003.

SECTION .1100 – TRAUMA SYSTEM DESIGN

10A NCAC 13P .1101 STATE TRAUMA SYSTEM

(a) The state trauma system consists of regional plans, policies, guidelines and performance improvement initiatives by the RACs and monitored by the OEMS.
(b) The OEMS shall require that each hospital select a Regional Advisory Committee (RAC). If a hospital does not exist in a given county, the EMS System for the county shall select the RAC. Each RAC shall include at least one Level I or II trauma center. Any hospital changing its affiliation shall report the change in writing to the OEMS within 30 days of the date of the change.
(c) The OEMS shall notify each RAC of its hospital and county membership.

History Note: *Authority G.S. 131E-162;*
Temporary Adoption Eff. January 1, 2002;
Eff. April 1, 2003.

10A NCAC 13P .1102 REGIONAL TRAUMA SYSTEM PLAN

(a) A Level I or II trauma center shall facilitate development of and provide RAC staff support that shall include, at a minimum, the following:
(1) The trauma medical director(s) from the lead RAC agency;
(2) Trauma nurse coordinator(s) or program manager(s) from the lead RAC agency.
(b) The RAC membership shall include, at a minimum, the following:
(1) The trauma medical director(s) and the trauma nurse coordinator(s) or program manager(s) from the lead RAC agency;
(2) If on staff, an outreach coordinator(s) or designee(s), as well as an identified RAC registrar or designee(s) from the lead RAC agency;
(3) A senior level hospital administrator;
(4) An emergency physician;
(5) An Emergency Medical Services representative;
(6) A representative from each hospital participating in the RAC;
(7) Community representatives;
(8) An EMS System physician involved in medical oversight.
(c) The RAC shall develop and submit a plan within one year of notification of the RAC membership, or for existing RACs within six months of the implementation date of this rule, to the OEMS containing at a minimum:
(1) Organizational structure to include the roles of the members of the system;
(2) Goals and objectives to include the orientation of the providers to the regional system;

(3) RAC membership list, rules of order, terms of office, meeting schedule (held at a minimum of two times per year);
(4) Copies of documents and information required by the OEMS as defined in Rule .1103 of this Section;
(5) System evaluation tools to be utilized;
(6) Written documentation of regional support for the plan; and
(7) Performance improvement activities to include the RAC Registry.

(d) The RAC shall submit to the OEMS an annual progress report that assesses compliance with the regional trauma system plan and specifies any updates to the plan.

(e) Upon OEMS' receipt of a letter of intent for initial Level I or II trauma center designation pursuant to Rule .0904 (b) of this Subchapter, the applicant's RAC shall be provided the applicant's data from OEMS to review and comment. This data which should demonstrate the need for the trauma center designation must include at a minimum:

(1) The population to be served and the extent to which the population is underserved for trauma care with the methodology used to reach this conclusion;
(2) Geographic considerations to include trauma primary and secondary catchment area and distance from other trauma centers; and
(3) Trauma patient volume and severity of injury for the facility for the 24-month period of time preceding the application. The trauma center shall show that its trauma service will be taking care of at least 200 trauma patients with an Injury Severity Score (ISS) greater than or equal to 15 during the first two-year period of its designation. This criteria shall be met without compromising the quality of care or cost effectiveness of any other designated Level I or II trauma center sharing all or part of its catchment area or by jeopardizing the existing trauma center's ability to meet this same 200-patient minimum.

(f) The RAC has 30 days to comment on the request for initial designation.

(g) The RAC shall also be notified of the OEMS approval to submit an RFP so that necessary changes in protocols can be considered.

History Note: *Authority G.S. 131E-162;*
Temporary Adoption Eff. January 1, 2002;
Eff. April 1, 2003.

10A NCAC 13P .1103 REGIONAL TRAUMA SYSTEM POLICY DEVELOPMENT

The RAC shall oversee the development, implementation, and evaluation of the regional trauma system to include:

(1) Public information and education programs to include system access and injury prevention;
(2) Written trauma system guidelines to address the following:
    (a) Regional communications;
    (b) Triage;
    (c) Treatment at the scene and in the pre-hospital, inter-hospital, and Emergency Department to include guidelines to facilitate the rapid assessment and initial resuscitation of the severely injured patient, including primary and secondary survey. Criteria addressing management during transport shall include continued assessment and management of airway, cervical spine, breathing, circulation, neurologic and secondary parameters, communication, and documentation.
    (d) Transport to determine the appropriate mode of transport and level of care required to transport, considering patient condition, requirement for trauma center resources, family requests, and capability of transferring entity.
    (e) Bypass procedures that define:
        (i) circumstances and criteria for bypass decisions;
        (ii) time and distance criteria; and
        (iii) mode of transport which bypasses closer facilities.
    (f) Scene and inter-hospital diversion procedures that shall include delineation of specific factors such as hospital census or acuity, physician availability, staffing issues, disaster status, or transportation which would require routing of a patient to another trauma center.
(3) Transfer agreements (to include those with other hospitals, as well as specialty care facilities such as burn, pediatrics, spinal cord, and rehabilitation) which shall outline mutual understandings between

facilities to transfer/accept certain patients. These shall specify responsible parties, documentation requirements, and minimum care requirements.

(4) A performance improvement plan that includes:

(a) A regional trauma peer review committee of the RAC;

(i) whose membership and responsibilities are defined in G.S. 131E-162; and

(ii) continuously evaluates the regional trauma system through structured review of process of care and outcomes; and

(b) The existing trauma registry database and the RAC registry database, once operational, that report quarterly or as requested by the OEMS.

History Note: *Authority G.S. 131E-162;*
Temporary Adoption Eff. January 1, 2002;
Eff. April 1, 2003;
Amended Eff. January 1, 2004.

SECTION .1200 - TRAUMA SYSTEM DESIGN

10A NCAC 13P .1201 STATE TRAUMA SYSTEM PLAN
10A NCAC 13P .1202 REGIONAL TRAUMA SYSTEM PLAN
10A NCAC 13P .1203 REGIONAL TRAUMA SYSTEM POLICY DEVELOPMENT

History Note: *Authority G.S. 131E-162;*
Eff. August 1, 1998;
Repealed Eff. January 1, 2004.

SECTION .1300 - FORMS

10A NCAC 13P .1301 SOURCE OF FORMS AND DOCUMENTS

History Note: *Authority G.S. 131E-162;*
Eff. August 1, 1998;
Repealed Eff. January 1, 2004.